

CONTINUING CONCERNS OVER IMPORTED PHARMACEUTICALS

HEARING BEFORE THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS OF THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED SEVENTH CONGRESS FIRST SESSION

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CONTINUING CONCERNS OVER IMPORTED PHARMACEUTICALS

THURSDAY, JUNE 7, 2001

**HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Washington, DC.**

The subcommittee met, pursuant to notice, at 10 a.m., in room 2123, Rayburn House Office Building, Hon. James C. Greenwood, (chairman) presiding.

Members present: Representatives Greenwood, Bilirakis, Stearns, Gillmor, Largent, Burr, Whitfield, Bass, Deutsch, Stupak, DeGette, and Dingell (ex officio).

Staff present: Alan Slobodin, majority counsel; Ray Shepherd, majority counsel; Will Carty, legislative clerk; and Chris Knauer, minority counsel.

Mr. GREENWOOD. Good morning. A quorum being present, this hearing of the Oversight and Investigations Subcommittee of the House Energy and Commerce Committee will come to order.

The Cambridge Dictionary of American English defines the word "huckster" as a person who sells things or puts forward ideas in a very determined way that is often not completely honest.

Sadly, there is a long and infamous history of hucksterism in America. Today, we are here to examine the latest incarnation of this unscrupulous practice of selling people what they either don't need or shouldn't buy. In this case, it is the sale of unapproved mis-branded or adulterated drugs.

Usually ineffectual, and often unsafe, and increasingly over the Internet, the disreputable promoters of these illicit products have added a new twist to the way that modern day stake oil salesmen prey on the needy and the unsuspecting.

Their model might very well be there is a sucker logging on every minute. A few weeks ago, Congressmen Deutsch, Stupak, and I visited the international mail facility near Dulles Airport, and what we found was truly frightening.

And these are some examples of the drugs that we found. This one is labeled, "Jungle Juice." It is amyl nitrite and it is a drug that is abused, usually by young people on dance floors I am told, and in discos.

This is a vial of drugs. It is a powder labeled, "Gamma hydroxybuterate." We have no idea what it really is. We found all kinds of pills, and a virtual drug cabinet full of all kinds of products; steroids, illegal drugs, legal drugs, misbranded drugs, all very dangerous to the American public.

Overall, I believe that prescription drugs in the U.S. are extremely safe, but it is important to remember that the risk is not zero. There is no magic force-field that protects the U.S. from imported counterfeit or diverted products.

We must be aware of the latest threats in the global pharmaceutical market and we must deal with them. Perhaps nothing more clearly illustrates the dangers of drug importation than the evidence turned up in a joint U.S. and Thai customs enforcement effort in March 2001.

Called Operation Chokepoint, it shows what lurks behind some of these foreign based Internet pharmacies. This operation targeted thousands of illegal pharmaceutical shipments of viagra and steroids exported from Thailand by mail from a notorious Internet pharmacy to U.S. customers.

The results of the operation showed a British national, still under treatment for hepatitis, operating an illegal pharmaceutical processing center in his residence, processing the drugs in a filthy, vermin infested kitchen.

Representatives in the U.S. Congress enact the laws to protect consumers from the dangers of unapproved, misbranded, or adulterated drugs. As such Representatives, we have a responsibility to raise public awareness about these risks, and to put an end to them.

The subcommittee is particularly concerned about the dangers of personal importation. In 1998, in response to concerns about the personal importation of controlled substances at the Mexican land border, the Congress enacted legislation that required a valid U.S. prescription for any personal import of a controlled substance that was more than 50 dosage units.

Unfortunately, it appears from the committee's staff's investigation that this 50 dosage unit policy has become well known and exploited by drug traffickers. One can even find controlled substances blister-packed in 50 dosage units amounts.

Consider also the massing of pharmacies that provide easy access to controlled substances at our southern borders. For example, in Tijuana, Mexico, it is estimated that there are approximately 1,700 pharmacies.

In contrast, 20 miles north in San Diego, California, which has roughly the same population, there are 125 pharmacies. Clearly, there is a need to further strengthen Federal policy in the area of personal imports of controlled substances.

I want to note my particular appreciation to Congressman John Dingell, the ranking member of the full committee, for forcefully raising this important public safety and public health issue.

Mail deliveries represent another personal importation problem. In January and February of 2001, the FDA conducted a pilot program with the Customs Service on mail deliveries of prescription drugs at the international mail facility at Los Angeles.

The FDA was only able to review 1,908 of nearly 16,000 parcels that came in, roughly 12 percent. Out of these, 554 were ultimately refused entry. A large percentage of the 554 refused entries were shipped via a South Pacific Republic called Vanuatu.

It is believed that those shipments were from a single source currently under criminal investigation. Extrapolating from the pilot

program data nationally, it is estimated that up to 200,000 parcels per month could be coming into the U.S. unexamined.

Clearly, a serious policy decision needs to be made and new procedures instituted. What are the dangers of the prescription drugs that are allowed in? We will hear of one tragic story from Edwin and Helen Rode.

I want to thank Reverend and Mrs. Rode for testifying at this hearing. It takes a lot of courage to relate their painful experience publicly, but by stepping forward, they hope to save the lives of others.

But what about unsuspecting customers who are getting drugs within the U.S. health care delivery system? What are the risks to them of purchasing counterfeit or substandard drugs? Recent events in the U.S. pharmaceutical market have justified this subcommittee's vigilance over counterfeiting.

Last month, three different drug companies reported finding counterfeit versions of their drugs in the U.S. One bogus drug was for treating patients with AIDS wasting disease, a particular vulnerable population.

So far there do not appear to be any life threatening adverse events linked to the counterfeits, but they did make their way on to pharmacy shelves and into patient's medical cabinets.

I want to thank the Chairman of the Energy and Commerce Committee, Congressman Billy Tauzin, for his support of this investigation, and hearing about imported drugs. I also want to thank the ranking minority member of the subcommittee, Congressman Peter Deutsch, for his support and interest in this investigation.

Likewise, I express my appreciation to Congressman Bart Stupak for his particular participation and contribution to this subcommittee's efforts. I am well aware of the hard work and the preparation for these hearings by all of the witnesses on behalf of the subcommittee, and I thank you and I look forward to your testimony.

[The prepared statement of Hon. James C. Greenwood follows:]

PREPARED STATEMENT OF HON. JAMES C. GREENWOOD, CHAIRMAN, SUBCOMMITTEE
ON OVERSIGHT AND INVESTIGATIONS

INTRODUCTION

When the subject is pharmaceuticals, people usually talk about the high prices. But today's hearing will show we still also need to pay attention to safety.

We in Congress are acutely aware of the problem of high prices of prescription drugs in the U.S. About a third of our elderly are without access to adequate prescription drug coverage. Many Americans, especially our senior citizens on fixed incomes, struggle to balance their finances to pay for prescription drugs that help keep them alive or maintain a decent quality of life.

Out of these desperate circumstances, some cash-strapped Americans are traveling to border pharmacies to obtain what they believe are cheaper versions of the U.S. drugs in Mexico or Canada. Some Americans are ordering drugs through the mail from foreign-based internet pharmacies to obtain prescription drugs without real physician supervision. Perhaps it is a measure of the success of the high regulatory and industry standards in the U.S. that many Americans in their pursuit of affordable medicine appear to take the safety of prescription drugs for granted.

However, what we will learn today, is that drugs obtained from outside the United States without proper controls pose real risks to American consumers. This hearing will examine these risks by focusing on four particular areas of continuing concerns over imported pharmaceuticals:

1. controlled substances from Mexican border pharmacies;
2. prescription drugs ordered from foreign-based internet pharmacies;

3. counterfeit or substandard bulk drugs; and
4. international pharmaceutical counterfeiting and diversion.

In all of these areas, there is a mass of evidence from studies and investigations that shows the safety risks. I understand that some Americans who feel desperate are willing to take risks purchasing prescription drugs from a border pharmacy or a foreign-based internet pharmacy. Under current circumstances, I don't want to interfere with seniors who are desperately looking for cheaper buys. But I feel sure that many senior citizens don't want to see their grandchildren harmed by controlled substances from border pharmacies or drugs obtained without a prescription from some phantom, foreign website.

Recent events in the U.S. pharmaceutical market have justified the Subcommittee's vigilance over counterfeiting. Last month, three different drug companies reported finding counterfeit versions of their drugs in the U.S. One bogus drug was for treating patients with AIDS wasting disease, a particularly vulnerable population. Another counterfeit purported to be a growth hormone that contained human insulin, which could be deadly to some individuals. The third fake drug was labeled as an anti-infective that had no active ingredient. So far, there do not appear to be any life-threatening adverse events linked to the counterfeits, but they did make their way to pharmacy shelves.

We have a responsibility to raise public awareness about the dangers of unapproved, misbranded or adulterated drugs, these risks, and to help minimize these risks through public education, working with the Administration to take sensible and restrained administrative actions, and passing new legislation, if necessary. I want Americans to get cheaper prescription drugs in the U.S. I don't want any Americans hurt in trying to get cheaper drugs from abroad.

BACKGROUND: THE FOOD, DRUG & COSMETICS ACT

Prescription drugs are highly regulated and require physician supervision for a reason. Drugs are inherently dangerous unless they are manufactured precisely and properly, dosed correctly, and used appropriately. When used under competent physician care and in accordance with instructions, drugs are life-saving. But there is often not a large margin between life and death.

For these reasons and others, it is illegal under the federal Food, Drug and Cosmetic Act to import misbranded, adulterated or unapproved prescription drugs. However, in a bow to common sense, the FDA decided over 40 years ago not to strictly enforce the Act against U.S. residents who obtained unapproved foreign-made prescription drugs to treat sickness or injury while on travel in a foreign country. Over time FDA created a guidance on personal importation of prescription drugs that in effect says for reasons of enforcement priorities and limited resources, FDA will not enforce the Act against U.S. residents who bring in a 90-day supply of foreign drugs for medical purposes either from traveling abroad or through mail delivery.

With regard to personal importation, the Subcommittee is particularly concerned about two areas: (1) controlled substances obtained at the land border pharmacies (especially Mexico), and (2) prescription drugs obtained through mail deliveries. Controlled substances represent the most dangerous class of prescription drugs, because they can be addicting, and even deadly when used non-medically. Because of their high abuse potential, these prescription drugs are scheduled under federal law requiring additional regulation.

BORDER CROSSINGS

In 1998, in response to concerns about the personal importation of controlled substances at the Mexican land border, the Congress passed an amendment to the Controlled Substances Import and Export Act. That amendment required a valid U.S. prescription for any personal import of a controlled substance that was more than 50 dosage units. Perhaps sensing that this 50-dosage unit law represented an opportunity for clearer guidance to overwhelmed Customs border inspectors, some in the Customs Service interpreted the 1998 amendment as justifying an enforcement practice that would allow personal imports of 50 dosage units or less for each drug per border crossing.

Unfortunately, it appears from the Committee staff's investigations at the Southwest border crossings, internet postings and chat rooms, and other information, that this 50-dosage unit policy has become well-known and exploited by drug traffickers and individuals interested in bringing in controlled substances for abuse purposes. One can even find controlled substances blister-packed in 50-dosage unit amounts.

Although we lack comprehensive and definitive data on controlled substances importation, it is reasonable to observe that the 50-dosage unit policy is contributing

to a national drug abuse problem. Consider the massing of pharmacies that provide easy access to controlled substances at our borders. For example, in Tijuana, Mexico, there are estimated to be up to 1700 pharmacies, up from 500 pharmacies in 1997. In contrast, twenty miles north, in San Diego, California, there are only 125 pharmacies.

In December 2000, the Texas Commission on Alcohol and Drug Abuse noted that a major substance abuse problem is Mexican pharmacies selling many controlled substances to U.S. citizens who declare these drugs and bring in personal import amounts into Texas. We will hear testimony from Landon Gibbs of the Virginia State Police about the emerging abuse problem of one controlled substance called oxycontin, a powerful painkiller drug with a 12-hour time-release targeted by drug traffickers because of the huge narcotic rush when the drug is crushed and snorted. Although the vast majority of abuse cases involves drug unlawfully obtained within the U.S., recent investigations indicate some oxycontin is coming from Mexico, probably some through personal importation from Mexico.

In response to the Committee's bipartisan concerns, several federal agencies—the Office of National Drug Control Policy, the Drug Enforcement Administration, the FDA, and the Customs Service—have been meeting to develop recommendations for strengthening federal policy in the area of personal imports of controlled substances. I understand that the Drug Enforcement Administration has developed a proposal that we hope to be a vast improvement over the status quo. I look forward to hearing about this proposal and discussion of this issue with our witnesses. I want to note my particular appreciation to Congressman John Dingell, the Ranking Member of the Full Committee, for forcefully raising this important public safety and public health issue.

MAIL DELIVERIES

Mail deliveries represent another personal importation problem. In the last few years, especially with the explosion of internet pharmacies, personal mail deliveries of prescription drugs have skyrocketed, overwhelming the Customs Service and the FDA. In January-February 2001, the FDA conducted a pilot program with the Customs Service on mail deliveries of prescription drugs at the international mail facility at Los Angeles.

Typically, the Customs Service screens the parcels by sight and through an x-ray machine. Customs sets aside the parcels of prescription drugs for an FDA officer to review. The FDA officer usually comes for a half-day, once a week, to review the parcels. Under the pilot program, two FDA officers were on-site, five-days a week, processing the set-aside parcels for 30 days. Even under these ideal circumstances, FDA was only able to review 1,908 parcels out of a possible 16,000 or only about 12% of the likely universe of prescription-drug parcels. Out of these parcels, FDA detained about 700 out of the 1900, because they appeared violative. Out of the 700 detained parcels, 554 were ultimately refused entry, usually because it was determined that the mail order lacked a valid prescription. A large percentage of the 554 refused entries were shipped via a South Pacific republic called Vanuatu and New Zealand. It is believed that those shipments were from a single source currently under criminal investigation. It is important to note that the parcels that FDA is unable to review are released. Extrapolating from the pilot program data nationally, it is estimated that up to 200,000 parcels per month could be coming in unreviewed.

In September 2000 the Customs Service conducted a study called Operation Safe-guard of two U.S. facilities showed that none of the pharmaceuticals examined were reimportations of U.S. manufactured drugs. None of the 512 parcels fulfilled all the personal use requirements. Only three parcels had evidence of medical supervision and ten percent of the parcels analyzed contained no active ingredients.

What are the dangers of the prescription drugs that are allowed in? We will hear of one tragic story from Edwin and Helen Rode. Their son, Todd, was found dead on November 16, 1999. They believe his death was a direct result of prescription drugs obtained through the mail from a foreign-based internet pharmacy. Although Todd was being treated for severe depression, he ordered a combination of prescription drugs without any physical examination by a physician. The medical examiner's report states that some of these drugs were ingested by Todd at the time of his death. I want to thank Reverend and Mrs. Rode for testifying at this hearing. It takes a lot of courage to relate their painful experience publicly. But by stepping forward, they may help save some lives.

O&I FIELD TRIP TO DULLES AIRPORT

Just a few weeks ago, Congressmen Deutsch, Stupak, and I visited the international mail facility near Dulles Airport. We viewed firsthand the processing of

prescription drug parcels. Here is one example. Many of these parcels contained prescription drugs that had been withdrawn from the US market, highly dangerous combinations of drugs for one person, drugs lacking labeling or instructions, drugs masked as something else or not in its original container. The overwhelming numbers of prescription-drug parcels is a daunting challenge, that would require a tremendous and unrealistic increase in personnel and resources. Even if such an increase occurred, the legal requirements in processing parcels impose massive burdens. Clearly, a serious policy decision needs to be made and new procedures considered. In response to a bipartisan inquiry in this area, the FDA in consultation with the Customs Service has devised several proposals for improving the public health protections related to mail deliveries. These proposals and a recommendation are pending with the Secretary of Health and Human Services. I look forward to working with the Secretary to move in a reasonable and responsible way.

In the area of personal importation, individuals usually are in some way assuming some risk. But what about unsuspecting consumers who are getting drugs within the U.S. healthcare delivery system? Are there any risks to them of getting counterfeit or substandard drugs? Over the last decade, there has been a surge in shipments of bulk drugs or "active pharmaceutical ingredients" (APIs) from overseas. About 70-80% of brand-name APIs and 90-95% of generic APIs are made overseas. Any foreign firm that makes bulk ingredients for the U.S. market must be inspected by the FDA. This surge of imports has overwhelmed FDA and outstripped its inspectional resources. Last year, the FDA advised the Committee that 242 foreign API firms appeared to have shipped misbranded drugs to the U.S. in 1999 but were never inspected by the FDA.

Even for those firms that have been inspected, the Subcommittee's past investigations have shown how the approved foreign firm in a few cases becomes the front for counterfeit or unapproved bulk drugs shipped to the U.S. Sophisticated counterfeiting in the chemistry and documentation of the drugs is difficult to detect. Last year's Subcommittee hearing revealed a link between serious reactions in a 155 American patients from an antibiotic and a Chinese bulk drug manufacturer. The FDA committed to a number of strategies for handling imported counterfeit and unapproved drugs. The Subcommittee will want to learn how the FDA has approved its intelligence gathering on counterfeiting. We will want to find out how the FDA plans to use its personnel and equipment to better monitor U.S. ports of entry. We are also interested in what, if any, security measures FDA has added and what additional resources may be needed.

Overall, prescription drugs in the U.S. are extremely safe. But it is important to remember that the risk is not zero. There is no magic force-field that protects the U.S. from imported counterfeit or diverted product. We must be aware of the latest threats in the global pharmaceutical market and deal with them. We are very fortunate to have some of the leading experts on pharmaceutical counterfeiting and diversion before us today. Their testimony should greatly assist the Subcommittee's understanding of the issues.

I want to thank the Chairman of the Energy and Commerce Committee, Congressman Billy Tauzin, for his support of this investigation and hearing about imported drugs. I also want to thank the Ranking Minority Member of the Subcommittee, Congressman Peter Deutsch, for his support and interest in this investigation. I likewise express my appreciation to Congressman Bart Stupak for his participation and contribution to the Subcommittee's efforts.

I am well aware of the hard work and the preparation for these hearings by all of the witnesses. On behalf of the Subcommittee, I thank you and look forward to your testimony.

Mr. GREENWOOD. With that, the Chair yields 5 minutes to the ranking member of the full committee, Mr. Dingell.

Mr. DINGELL. Thank you. I commend you for holding this hearing. I am saddened that we are again having to relearn the lessons that should be all too familiar to this Congress and to the subcommittee.

I will not elaborate on why we passed the Prescription Drug Marketing Act more than decade ago, because I believe that my views were made rather clear during last year's misguided attempt to lower drug prices by opening up the borders of the United States.

It is sufficient to say, however, that PDMA was specifically designed to prevent the kinds of activities we are reading about today, and discovering through the investigative efforts of this subcommittee.

Our systems for protecting the U.S. consumers from drugs of poor or dangerous quality are eroding, as recent evidence bears out: First, last week, it was discovered that not one, but three counterfeit drugs—Amgen-Serono, and Genentech—being the victimized innovator companies, have been found on the shelves of U.S. pharmacies.

It is unclear how much more exists, nor is it even clear where counterfeit drugs may next surface. Second, drugs shipped into this country by mail are overwhelming existing safeguards.

A recent pilot project conducted by the U.S. Customs Service and the Food and Drug Administration stopped 16,000 parcels as you mentioned in approximately 1 month that were being illegally shipped into the United States from foreign sources.

Because the regulatory system at the Nation's mail facilities is so overwhelmed and antiquated, 14,000 of these parcels were simply sent to the public without any regulatory review whatsoever.

And each day this scene is played out all over the country as hundreds, if not thousands, of products enter this country from abroad, and are sent to consumers without any safety check whatsoever.

In testimony that will be given today, the FDA now admits that approximately 2 million parcels containing FDA regulated products are entering the United States each year through international mail facilities, and most of these appear to have received no review by FDA, and are simply released by Customs.

This is not a new problem, and the FDA has been put on notice about it for years. Countless letters have been sent by this subcommittee, by the Customs, to FDA warning about the disintegration of the system and the hazards to the American public that stem therefrom.

Customs now freely admits that while the present system envisions that its staff hold all pharmaceuticals for FDA review when they enter the country, in reality most are delivered to consumers without knowing whether the drugs are safe, or without any testing whatsoever, to protect American consumers.

The FDA has so far demonstrated virtually no leadership on how to fix a failed system that springs in large measure from its own reimportation policies, and which we will examine today.

We have never expected miracles nor instant success, but after countless meetings, letters, discussions held by this subcommittee and Customs imploring the FDA to retool a system that places the public at severe risk, the FDA continues its foot dragging.

Third, prescription drugs are flooding into the country across the Mexican border. As you know, hundreds of Mexican pharmacies now dot the border from Texas to California on the Mexican side.

These pharmacists sell almost any type of drug to any person wishing to buy them. As in the words of one of our witnesses, "like some stores sell candy."

Buttressed by the FDA's vague and often misused and misunderstood personal use policy, thousands of U.S. residents cross the bor-

der each day to purchase their drugs from Mexico. This practice raises many public health and safety issues as we will hear from witnesses today.

How safe are these drugs and where do they come from? How were they manufactured and how have they been stored, and are the drugs counterfeit? Do they contain ingredients that will harm a consumer? Have good manufacturing practices—required by U.S. law—been practiced with regard to these pharmaceuticals?

Today, the testimony will suggest that the quality of Mexican drugs are often difficult, if not impossible, to determine. Some are perfectly safe, and some are counterfeit, and some contain no active ingredient, and others contain too much or too little active ingredient, posing similar risks.

Some, while clearly intended to be used under the close supervision of a doctor, are prescribed with little or no guidance, and most are prescribed without any significant follow-up supervision.

Despite having policies that encourage this activity, our government has almost no meaningful data from Customs, the Drug Enforcement Administration, or the FDA, to address these issues and questions.

And the budgets of the three agencies to carry out their responsibilities on these matters is grossly inadequate, as are the number of their personnel. Fourth, a questionable U.S. policy allows U.S. residents to legally bring in large amounts of potentially addictive and dangerous scheduled drugs without a prescription.

This policy is open to significant abuse, and I believe that we will find significant abuse is taking place. Last year in a letter that I sent to the FDA concerning this matter, I raised a number of questions relating to this problem by citing the rather sobering findings of Dr. Marvin Shepherd.

I note that he is here today, and I hope that he will receive the commendations of the committee. I thank him in advance for his testimony, as well as the excellent work that he has done on these matters over the years.

I also look forward to hearing from other witnesses, including the DEA and the White House, as to whether they believe that the potential good of the current policies outweigh the enormous opportunity and potential for abuse inherent in this policy.

Mr. Chairman, we indeed have several major policy problems coming together here today. Our citizens are looking to other countries to lower the cost of prescription drugs. They are increasingly taking desperate measures to obtain them.

They are traveling to Mexico, and they are buying drugs from Thailand, from China, from India, and everywhere else through the Internet. The Federal Government must act and soon to protect the safety of prescription drugs supplied, and American consumers.

The Federal Government, however, must do more. Some citizens are seeking alternative sources for drugs because they believe that they have no choice. The high costs of prescription drugs is driving them to take both legal and health risks.

We must face that reality and seek to address the problem of cost, whether it is through meaningful Medicare prescription drug benefits intended through the use of expanded generic drugs, the

exercise of governmental purchasing power, or otherwise, and action is needed and soon.

I hope that this hearing and continued subcommittee work can lead to the long and short term steps needed to resolve these problems, and again I commend you and thank you, Mr. Chairman.

[The prepared statement of Hon. John D. Dingell follows:]

PREPARED STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS
FROM THE STATE OF MICHIGAN

Mr. Chairman, thank you for holding this hearing. I am somewhat saddened that we are yet again having to go over lessons that should be all too familiar to this Subcommittee by now.

I will not elaborate on why we passed the Prescription Drug Marketing Act (PDMA) more than a decade ago because I believe I made my views rather clear during last year's misguided effort to attempt to lower drug prices by opening up our borders. Suffice it to say, however, that the PDMA was specifically designed to prevent the kinds of activities we are reading about today and discovering through the investigative efforts of this Subcommittee. Our systems for protecting U.S. consumers from drugs of poor or dangerous quality are eroding, as recent evidence bears out.

First, last week, it was discovered that not one, but three counterfeit drugs—Amgen, Serono, and Genentech being the victimized innovator companies—have been found on the shelves of U.S. pharmacies. It is unclear how much more exists, nor is it even clear where counterfeit drugs may surface next.

Second, drugs shipped into the country by mail are overwhelming existing safeguards. A recent pilot project conducted by the U.S. Customs Service (Customs) and the Food and Drug Administration (FDA) stopped 16,000 parcels in approximately one month that were being illegally shipped into the United States from foreign sources. Because the regulatory system at the nation's mail facilities is so overwhelmed and antiquated, 14,000 of these parcels were simply sent to the public without any regulatory review. And each day, this scene is played out all over the country as hundreds, if not thousands, of products enter this country from abroad, and are sent to consumers without any safety check. In testimony that will be given today, FDA now admits that approximately *two million parcels* containing FDA-regulated products are entering the U.S. each year through the international mail facilities, and most of these appear to receive no review by the FDA, and are simply released by Customs.

This is not a new problem, and FDA has been put on notice about it for years. Countless letters have been sent by this Subcommittee, and by Customs, to FDA warning about the disintegration of this system. Customs now freely admits that while the present system envisions that its staff hold all pharmaceuticals for FDA review when they enter the country, in reality, *most* are delivered to consumers without knowing whether these drugs are safe.

FDA has so far demonstrated little leadership on how to fix a failed system that springs in large measure from its own reimportation policies. We have never expected miracles or instant success. But after countless meetings, letters, and discussions held by this Subcommittee and Customs imploring FDA to retool a system that places the public at risk, the FDA continues its foot-dragging.

Third, prescription drugs are flooding into the country across the Mexican border. As you know, hundreds of Mexican pharmacies now dot the border from Texas to California. These pharmacies sell almost any type of drug to any person wishing to buy them—as in the words of one of our witnesses, “like some stores sell candy.”

Buttressed by FDA's vague and often misused personal-use policy, thousands of U.S. residents cross the border each day to purchase their drugs from Mexico. But this practice raises many public health and safety issues, as we will hear from the witnesses today. How safe are these drugs and where do they come from? How are they manufactured, and how are they stored? Are these drugs counterfeit? Do they contain ingredients that can harm a consumer?

Testimony today suggests that the quality of Mexican drugs is often difficult, if not impossible, to determine. Some are perfectly safe. Some are counterfeit and contain no active ingredient. Others can contain too much or too little active ingredient, posing similar risks. Some, while clearly intended to be used under the close supervision of a doctor, are prescribed with little or no guidance, and most are prescribed with little or any followup supervision.

Despite having policies that clearly encourage this activity, our government has almost no meaningful data from Customs, the Drug Enforcement Administration (DEA), or the FDA to address any of these issues and questions.

Fourth, a questionable U.S. policy allows U.S. residents to legally bring in potentially large amounts of potentially addictive and dangerous scheduled drugs without a prescription. This policy is open to significant abuse. Last year, in a letter I sent to the FDA concerning this matter, I raised a number of questions relating to this problem by citing the rather sobering findings of Dr. Marvin Shepherd. I see that he is before us today, and I thank him in advance for his testimony as well as the excellent work he has done on this matter over these years. I also look forward to hearing from our other witnesses, including the DEA and the White House, on whether they believe the potential good outweighs the potential abuse inherent in this policy.

Mr. Chairman, indeed, we have several major policy problems coming together here. Our citizens are looking to other countries for lower cost prescription drugs, and are increasingly taking more desperate measures to obtain them. They are traveling to Mexico. They are buying drugs from Thailand, China, India, and everywhere else, through the Internet. The Federal Government must act, and soon, to protect the safety of the prescription drugs supply.

But the Federal Government must do more. Some citizens are seeking alternative sources for drugs because they believe that they have no choice. The high cost of many prescription drugs is driving them to take both legal and health risks. We must face that reality and seek to address the problem of cost. Whether that is through a meaningful Medicare prescription drug benefit, expanded use of generic drugs, exercise of governmental purchasing power, or otherwise, we must act, and soon.

I hope this hearing, and continued Subcommittee work, can lead to both the short-term and long-term steps needed to solve these problems.

Mr. GREENWOOD. The Chair thanks the ranking member of the full committee, and recognizes now the chairman of the Subcommittee on Health, Mr. Bilirakis, from Florida.

Mr. BILIRAKIS. Thank you very much, Mr. Chairman. I, too, am grateful that you are holding this hearing, and of your interest in this particular subject. Access to affordable prescription drugs, particularly for our seniors, is a very serious concern.

Many Members of Congress, myself included, and particularly myself because of the district that I represent in Florida, have heard from constituents who are upset about paying more for prescription drugs than citizens of other countries.

And some of these Americans travel outside the United States to purchase their pharmaceuticals. The Food and Drug Administration currently allows under certain circumstances and bounds for patients to bring in a 3 month supply of prescription drugs for their personal use.

Today, drugs are often purchased by an individual through the mail or the Internet. However, the policy allowing the importation for these uses was not intended, I think, to promote these practices on such a broad, broad basis.

As I understand it, the consensus view within the FDA and the Customs Service is generally not to interfere with seniors who decide to assume the health risks of buying drugs for personal use.

Furthermore, the FDA and Customs are overwhelmed by the amount of drugs coming in over our borders and through the mail, and I know, Mr. Chairman, that I have heard you talk about your visit out to Dulles and seeing the amount of drugs coming in and how it has overwhelmed Customs out there.

Over the last decade, there has also been an increase in the shipments of bulk or active pharmaceutical ingredients from overseas.

Any foreign firm that makes bulk ingredients for the U.S. market must be inspected by the FDA.

Therefore, it is important to understand the impact of these developments on the agency's limited resources. I am hopeful that today's hearing will shed light on these and other important issues related to the safety of imported pharmaceuticals.

Mr. Chairman, I have to go and do an organ transplant type of a thing in a few minutes, and so I will break loose, but I would like to come back, because this is of great interest. Thank you very much, sir.

[The prepared statement of Hon. Michael Bilirakis follows:]

PREPARED STATEMENT OF HON. MICHAEL BILIRAKIS, A REPRESENTATIVE IN
CONGRESS FROM THE STATE OF FLORIDA

Thank you Chairman Greenwood for holding today's hearing on the safety of imported pharmaceuticals. I look forward to hearing from our witnesses and learning more about this important issue.

Access to affordable prescription drugs, particularly for our seniors, is a serious concern. Many Members of Congress—myself included—have heard from constituents who are upset about paying more for prescription drugs than citizens of other countries. Some of these Americans now travel outside the United States to purchase their pharmaceuticals.

The Food and Drug Administration (FDA) currently allows patients to bring in a three-month supply of prescription drugs for their personal use. Today, drugs are often purchased by an individual through the mail or the Internet. However, the policy allowing importation for personal use was not intended to promote these practices on such a broad basis.

As I understand it, the consensus view within the FDA and the Customs Service is generally not to interfere with seniors who decide to assume the health risks of buying drugs for personal use. Furthermore, FDA and Customs are overwhelmed by the amount of drugs coming in over our borders and through the mail.

Over the last decade, there has also been an increase in the shipments of bulk or "active pharmaceutical ingredients" from overseas. Any foreign firm that makes bulk ingredients for the U.S. market must be inspected by the FDA. Therefore, it is important to understand the impact of these developments on the agency's limited resources. I am hopeful that today's hearing will shed light on these and other important issues related to the safety of imported pharmaceuticals.

Mr. GREENWOOD. Hopefully that is testimony and not surgery. The Chair thanks the subcommittee chairman and recognizes the ranking member of the Oversight and Investigations Subcommittee, the gentleman from Florida, Mr. Deutsch.

Mr. DEUTSCH. Thank you, Mr. Chairman, and thank you for holding this hearing. Mr. Chairman, this committee has always had a great interest in the safety of the U.S. drug supply, and has always had a rich tradition of monitoring any threats to that system.

Lately, however, there are a number of issues with which we must concern ourselves. Several years ago, this subcommittee began an investigation into how prescription drugs were being sold both domestically and internationally through the Internet.

When this subcommittee first began its inquiry only a handful of firms existed, and only a trickle of drugs were entering the U.S. as a result of these activities. It was predicted then that if this problem was not quickly addressed by the FDA and other key agencies that the existing systems used to process incoming parcels of mail would quickly be outpaced by the volume of foreign shipments.

This prediction has become a reality, Mr. Chairman. But once merely an annoyance to the regulatory system, the volume of un-

regulated drugs now entering the U.S. through the Nation's 13 international mail facilities threatens to undermine the original intent of the Prescription Drug Marketing Act, legislation passed by the Committee on Energy and Commerce for the purpose of protecting our citizens from adulterated or substandard drugs from abroad.

Currently, tens of thousands of unregulated parcels containing a variety of drug products enter the U.S. each week. U.S. Customs inspectors can't keep pace with the workload, nor do they have meaningful guidance or sufficient help from the FDA to properly process them.

Instead, the U.S. Customs is overwhelmed. They are often forced to release the shipments to the public without any FDA scrutiny. It now appears more the exception that the FDA examines the bulk of these incoming parcels.

The situation at many of these ports of entry has thus become a ticking public health time bomb. Indeed, the amount of wholly unregulated drug parcels coming into this country through our mail facilities is not trivial.

Just a few weeks ago, Mr. Stupak, Chairman Greenwood, and I, visited the Dulles Airport facility. What we found was sobering. Before our arrival, the U.S. Customs inspectors detained 167 parcels containing drugs in just 4 hours.

Most of what we saw was a haphazard collection of unmarked and misbranded drugs. Many contained no labels, while many drugs were mixed with other drugs. Some parcels had false declarations, while most contained no prescription nor any indication that a drug was being taken under supervision of a doctor or a pharmacist.

In recent pilot projects at the Los Angeles mail facility, Customs detained an astonishing 16,000 shipments in just over a 1-month period. But because the system used today is so archaic and understaffed, the FDA had time to examine only about 1,900 of these parcels.

What happened to the other 14,000 parcels? The same thing that happens every day across this country. They were released to the public without any FDA review. Were they safe? Who knows. Were they real? Who knows.

Were they properly stored? Who knows? But what is known is that this practice is the pharmaceutical version of Russian Roulette, placing the public at risk. Nevertheless, despite mounting evidence for the past several years that this system is spiraling out of control, and after receiving numerous letters from the U.S. Customs Service and this subcommittee to examine this system to put forth rational proposals on how to address this problem. The FDA, which is responsible for the system, has failed to act. Instead, by taking a head in the sand approach and ignoring years of warning signs, the agency inaction has only contributed to the chaos.

I look forward to this hearing and hearing from FDA, who is finally making proposals, specific proposals, to retool a very broken system.

Mr. Chairman, let me quickly shift gears here to mention another issue that we will be discussing today, which is the matter of drugs coming in from Mexico. Currently, tens of thousands of

U.S. citizens are making monthly trips to Mexico to buy a group of drugs from the hundreds of pharmacies that exist within easy walking distance of the border.

Currently, a number of policies now exist that allow and may even encourage U.S. citizens to shop for their drugs in Mexico. Aside from the fact that our regulatory agencies seem to know almost nothing about the quality or sources, many of our witnesses will voice concerns about some of these practices.

For example, current policy allows for a U.S. citizen to walk across the border and bring back a vast array of powerful and potentially addictive controlled substances as long as they are declared to U.S. Customs upon reentering the U.S.

This means that while U.S. citizens must have a prescription from a doctor to obtain a potentially dangerous substance in San Diego, if they walk across the border to Tijuana, they can buy an almost endless supply of Schedule II to V drugs as long as each drug does not exceed 50 tablets.

Why is that, Mr. Chairman? As many controlled substances also have inexpensive generic versions available here in the U.S., serious questions must be raised about the objective of such a policy.

And as Dr. Shepherd, who will testify here later, points out, evidence suggests that many of these drugs are being purchased by younger persons for recreational use or resale on the street.

But whatever our decisions are to be in this regard, at a very minimum, we need better information. If we intend to allow persons to obtain drugs from Mexico, we should better assess what risks are involved in this practice to at least allow U.S. citizens to make informed choices.

Currently, despite the fact that tens of thousands of U.S. Citizens purchase their drugs from Mexico every month, there is little data to tell us what the public health implications of such practices are.

If we are going to have policies that permit and even encourage such behavior, we must better assess all the risks involved. Let me conclude, Mr. Chairman, by also saying that we must also attempt to analyze why is it that many U.S. citizens are purchasing their medications through these poorly regulated channels.

This is not an easy task, but it is an essential ingredient in attempting to address some of the public safety issues raised by the activities that we will discuss today. Clearly, while some might be seeking drugs for their abuse potential, others clearly travel to Mexico or purchase their drugs through the Internet because they feel such practices save them money.

In some cases involving certain countries, this may be a dangerous practice. Providing better and affordable alternatives to these practices is an essential stepping stone toward effective solutions to some of these problems.

I believe that if we wish to be successful in addressing the massive amounts of drugs entering the U.S. through unregulated channels, we need to come to an agreement on how to make prescription drugs more affordable for all U.S. citizens that need them, and I welcome this debate.

Thank you, Mr. Chairman, and I look forward to hearing from the witnesses today.

[The prepared statement of Hon. Peter Deutsch follows:]

PREPARED STATEMENT OF HON. PETER DEUTSCH, A REPRESENTATIVE IN CONGRESS
FROM THE STATE OF FLORIDA

Thank you Mr. Chairman, and thank you for holding this hearing.

Mr. Chairman, this Committee has always had a great interest in the safety of the U.S. drug supply and it has always had a rich tradition of monitoring any threats to that system. Lately, however, there are a number of issues with which we must concern ourselves.

Several years ago, this Subcommittee began an investigation into how prescription drugs were being sold both domestically and internationally through the Internet. When this Subcommittee first began its inquiry, only a handful of firms existed and only a trickle of drugs were entering the U.S. as a result of these activities.

It was predicted then that if this problem was not quickly addressed by the FDA and other key agencies, existing systems used to process incoming parcels of mail would quickly be out-paced by the volume of foreign shipments. That prediction has become a reality, Mr. Chairman.

While once merely an annoyance to the regulatory system, the volume of unregulated drugs now entering the U.S. through the nation's 13 international mail facilities threatens to undermine the original intent of the Prescription Drug Marketing Act, legislation passed by the Committee on Energy and Commerce for the purpose of protecting our citizens from adulterated or substandard drugs from abroad.

Currently, tens of thousands of unregulated parcels containing a variety of drug products enter the U.S. each week. U.S. Customs inspectors can't keep pace with the workload, nor do they have meaningful guidance or sufficient help from FDA to properly process them.

Instead, U.S. Customs is overwhelmed. They are often forced to release the shipments to the public without any FDA scrutiny. It now appears more the exception than the rule that FDA examines the bulk of these incoming parcels. The situation at many of these ports of entry has thus become a ticking public-health time bomb.

Indeed, the amount of wholly unregulated drug parcels coming into this country through our mail facilities is not trivial. Just a few weeks ago, Mr. Stupak, Chairman Greenwood, and I visited the Dulles airport facility.

What we found was sobering. Before our arrival, U.S. Customs inspectors detained 167 parcels containing drugs in just four hours. Most of what we saw was a haphazard collection of unmarked and misbranded drugs. Many contained no labels, while many drugs were mixed with other drugs. Some parcels had false declarations, while most contained no prescription nor any indication that the drug was being taken under the supervision of a doctor or a pharmacist.

In a recent pilot project at the Los Angeles mail facility, Customs detained an astonishing 16,000 shipments in just over a one-month period. But because the system used today is so archaic and understaffed, FDA had time to examine only about 1,900 of these parcels.

What happened to the other 14,000 parcels? The same thing that happens every day across this country—they were released to the public without any FDA review. Were they safe? Who knows. Were they real? Who knows. Were they properly stored? Who knows. But what is known is that this practice is the pharmaceutical version of Russian roulette, placing the public at risk.

Nevertheless, despite mounting evidence for the past several years that this system is spiraling out of control, and after receiving numerous letters from the U.S. Customs Service and this Subcommittee to examine this system to put forth rational proposals on how to address this problem, the FDA—which is responsible for this system—has failed to act. Instead, by taking a "head-in-the-sand" approach and ignoring years of warning signs, the agency's inaction has only contributed to the chaos. I look forward to hearing whether the FDA finally has any meaningful proposals on how to retool a very broken system.

Mr. Chairman, let me quickly shift gears here to mention another issue that we will be discussing today, which is the matter of drugs coming from Mexico.

Currently tens of thousands of U.S. citizens make monthly trips to Mexico to buy a myriad of drugs from the hundreds of pharmacies that exist within easy walking distance of the border. Currently, a number of policies now exist that allow—and may even encourage—U.S. citizens to shop for their drugs in Mexico. Aside from the fact that our regulatory agencies seem to know almost nothing about the quality or sources, many of our witnesses will voice concerns about some of these practices.

For example, current policy allows for a U.S. citizen to walk across the border and bring back a vast array of powerful and potentially addictive controlled substances, as long as they are declared to U.S. Customs upon reentering the U.S. This means

that while a U.S. citizen must have a prescription from a doctor to obtain a potentially dangerous substance in San Diego, if they walk across the border to Tijuana they can buy almost an endless supply of schedule II-V drugs, as long as each drug does not exceed 50 tablets. Why is that, Mr. Chairman?

As many controlled substances also have inexpensive generic versions available here in the U.S., serious questions must be raised about the objective of such a policy. And as Dr. Shepherd, who will testify later today, points out, evidence suggests that many of these drugs are being purchased by younger persons for recreational use or resale on the street.

But whatever our decisions are to be in this regard, at a very minimum we need better information. If we intend to allow persons to obtain drugs from Mexico we should better assess what risks are involved in this practice to at least allow U.S. citizens to make informed choices. Currently, despite the fact that tens of thousands of U.S. citizens purchase their drugs from Mexico every month, there is little data to tell us what the public health implications of such practices are. If we are going to have policies that permit and even encourage such behavior, we must better assess all risks involved.

Let me conclude, Mr. Chairman, by also saying that we must also attempt to analyze why it is that many U.S. citizens are purchasing their medications through these poorly regulated channels. This is not an easy task, but it is an essential ingredient in attempting to address some of the public safety issues raised by the activities we will discuss today. Clearly, while some might be seeking drugs for their abuse potential, others clearly travel to Mexico or purchase their drugs through the Internet because they feel such practices save them money. In some cases involving certain countries, this may be a dangerous practice. But providing better and affordable alternatives to these practices is an essential stepping stone toward effective solutions to some of these problems.

I believe that if we wish to be successful in addressing the massive amount of drugs entering the U.S. through unregulated channels, we need to come to agreement on how to make prescription drugs more affordable for all U.S. citizens that need them, and I welcome that debate.

Thank you, Mr. Chairman, and I look forward to hearing from our witnesses today.

Mr. GREENWOOD. The Chair thanks the gentleman, and recognizes for 5 minutes the gentleman from Michigan, Mr. Stupak.

Mr. STUPAK. Thank you, Mr. Chairman, and thank you for holding this very important hearing on imported pharmaceuticals, and thanks for your work on this issue.

Mr. Chairman, we are facing a problem of immense proportions and are simply unprepared to deal with it. Unregulated and unsupervised drugs are pouring into this country, and with the advent of Internet pharmacies, the volume of pharmaceutical products being shipped into the United States has exploded.

Unfortunately, the resources that we have put together to deal with this problem has not met the needs, and the hearing that we are holding today is the first of hopefully more hearings that we will have on this all too familiar topic for me.

In the last Congress, I, myself, Mr. Dingell, Mr. Klink, Mr. Waxman, and others, actually tried to introduce a bill, and did introduce a bill to specifically deal with the sale of prescription drugs through the Internet.

And I intend to reintroduce a very similar bill again shortly. This bill will help, but will not stop, the flow of unregulated drugs into this country. We simply cannot allow this situation to continue unchecked, and we need to work with all the authorities to make sure that when we do pass a bill that we get it right.

Mr. Chairman, you, I, and the ranking member, Mr. Deutsch, saw the problem of mail order prescription drugs first-hand several weeks ago on our trip down to the Dulles Airport mail facility.

Hundreds of packages of illegal drugs pulled from a mere 3 days worth of international mail lay on the tables in the Customs area for our inspection, and I suppose that some of those packages there are what we saw at Dulles.

The packages were breathtaking in their variety; pink pills, red pills, green pills, white pills, yellow liquid, brown liquid, clear liquid, capsules, tablets, powder, paste, blister packs, zipped lock baggies. You name it, it was there.

We saw pills stuffed in bras, pills stuffed in cotton, pills stuffed in carbon paper, because the smugglers think that the x-ray will be fooled with the carbon wrapped around their pills. And pills wrapped in birthday presents. All of these were headed to the American public.

American citizens have no idea if the pharmacy that they receive their pills from is an FDA-approved facility, or a vermin-filled kitchen table in a flophouse, run by an individual in Thailand with hepatitis, working with a prostitute as his assistant.

But I am sure that they have a very nice video web page or website to get us all to buy their drugs. And these are just the pills that the individuals order. It does not take into account or begin to address the problem of bulk and counterfeit drug ingredients and products, more and more which are showing up in today's health care market.

Mr. Chairman, a lot of us reviewed the report of the L.A. Airport, in which we looked at and found what was coming into L.A. in just 4 to 5 weeks. We have a list here today, and there were over 16,000 parcels that came in within that 4 to 5 weeks.

And in that 4 to 5 weeks, like in one parcel, three bottles of unknown medication, approximately 300 tablets. The tablets are green and the bottles are labeled in a foreign language. No English.

Or another one, 1,080 dosage units; 1,080 tablets of an unknown tablet, dark brown in color. That is what we are seeing coming through the mail. And today it is estimated that over 2 million parcels a year comes into this country unknown, unmarked, and where they are going, and what they contain. The American consumer has no idea.

And this number is only going to continue to grow unless we do something about it. What we need to do in today's hearing is not to simply figure out who is responsible for these illegal drugs coming into our country, but take some action, and take some action now.

The FDA has been asked time and time again for direction. Letter after letter has been sent to the FDA, not only from Customs, but also from this Congress and this subcommittee, asking for guidance.

These letters and pleas have not yielded any substantive answers, strategies, nor proposals. Because of the FDA's failure to act, what started out to be a small problem is now flooding this country.

It is time for the FDA to move off-center. We also have the 50 fill problem, 50 pills without prescription, at the Mexican border; and Mr. Dingell, and Mr. Deutsch, and others have spoke up today, and that needs to be addressed, and once again, we need to address it now.

We have in front of our committee today all the interested parties, and I hope that we can come up with a defined consensus on what should be done on each of these issues.

I look forward to continuing to work with you, Mr. Chairman, and others on this committee, on this very, very important and deadly matter. Thank you.

Mr. GREENWOOD. The Chair thanks the gentleman from Michigan, and recognizes for an opening statement for 5 minutes the gentlelady from Colorado, Ms. DeGette.

Ms. DeGette. Thank you, Mr. Chairman, and thank you for holding this hearing today. This is at least the third hearing in a row that we have had annually regarding the importation of pharmaceuticals.

I hope this hear that we can actually make some progress so that we don't find ourselves again next year about the same time in this same room, in the same chairs rehashing the information, when frankly our constituents' lives continue to be at risk.

I am hopeful that it won't take another t.v. expose, a newspaper series, some reporter ordering viagra for their dog, or worse, and seriously, an incident of patient deaths, and for meaningful action to be undertaken immediately.

As I said last year in my opening statement about this same time, on-line access to pharmaceuticals can be a wonderful tool and one that has opened up a whole new world of convenience to patients.

One thing that hasn't been focused on today is the ease with which chronic patients can get information and can easily get their prescription drugs on-line at a decent price.

That can be a benefit to patients.

I am the Co-Chair of the Congressional Diabetes Caucus, and for those with chronic long term illnesses, it can be an enormous convenience to use the Internet. But with this ease comes risks. One of the biggest risks as we have heard is the explosion in the counterfeit prescription drug market and its potential to do great harm to individuals.

Mr. Chairman, I know how this can affect a community, because it happened right in my district in Denver, Colorado. In 1998, six patients at a Denver hospital had toxic reactions to counterfeit pharmaceuticals.

According to Dr. Michael Earnest, who is a physician at the Denver Health Medical Center, failure of the FDA to adequately inform the hospital of the potential for counterfeit pharmaceuticals contributed to this frightening occurrence.

Health officials in other States according to U.S. News and World Report, have echoed this concern. This problem is beginning to be a real threat to the health of the American people when you can't even count on avoiding counterfeit pharmaceuticals in a hospital.

If the United States does not begin to seriously address this problem and step up oversight activities, there will be more counterfeit drugs in the United States and more Americans put in harm's way.

Improper oversight has permitted individuals to remove both the doctor's role of prescribing drugs and equally important the phar-

macist's role in providing the patient another source of medical advice.

We need to have standard policies regarding pharmaceutical purchases. It doesn't make sense to require a prescription for drugs purchased in the United States, but then to look the other way when someone walks back into the States with regulated substances, or purchases them on the Internet without a prescription.

We simply cannot any longer allow the elimination of important safeguards. Purchasing pharmaceuticals without the help of real doctors, or without the advance of real pharmacists, is extremely dangerous.

Mr. Chairman, these issues are a product of a larger living problem for our Nation; the explosion in the cost of health care, including pharmaceutical drugs. And Mr. Stupak talked about this for a moment.

One of the reasons that folks are turning toward these Internet pharmaceuticals or the border is because they are trying to obtain needed medications as a way to stretch or fix on limited budgets.

We cannot, however, lose sight of that larger story. We owe it to our constituents to provide protections wherever the pharmaceuticals are purchased. As Dr. Shepherd, who is testifying today, suggests, many purchases are not made by the Nation's poor and elderly to save costs.

Individuals who do not intend to personally use them purchase a significant amount of these drugs, and this is further substantiated by the DEA's testimony which we will hear today, which is stating that a healthy stream of people is going across the border to purchase controlled substances.

Enforcement of the current laws is going to be critically important in this effort. According to an FDA pilot program that ran for 30 days earlier this year, potentially 16,000 parcels could have been referred by Customs to the FDA.

Clearly, there is a torrential flood of prescription drugs entering the U.S. I think it is safe to assume that a large percent of them are illegal and potentially lethal. If controlling this flow is a matter of resources, Mr. Chairman, we need to know what the magnitude of the problem is, and we need to allocate the resources for enforcement of current laws.

I think it is important that we discuss today the current law, and whether that is being adequately enforced, and whether we need changes to the law or more resources; what is the extent of the problem, and what do we need to do to resolve the situation.

Mr. Chairman, I look forward to hearing the witnesses' testimony, and their responses to questions posed by members, and I yield back the balance of my time.

Mr. GREENWOOD. The Chair recognizes the arrival of Mr. Whitfield and Mr. Gillmor. Do either of those gentlemen have opening statements to make?

Mr. GILLMOR. I waive my opening statement.

Mr. WHITFIELD. I waive.

Mr. GREENWOOD. The gentlemen both waive their option of making an opening statement.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. CLIFF STEARNS, A REPRESENTATIVE IN CONGRESS
FROM THE STATE OF FLORIDA

Thank you Chairman Greenwood for holding this important hearing. I also want to thank our witnesses for being here today and I look forward to hearing their testimony.

Today we will hear about several very troubling aspects related to imported pharmaceuticals. A chief concern is that many individuals are purchasing pharmaceuticals along the Mexican borders. What many of these consumers may not know is that they may not necessarily be getting what they think they are purchasing. Without strict standards such as those required in the United States, these drugs could be nothing more than placebos, or could contain ingredients that could pose a health risk. In particular, seniors seek these cheaper prescription drugs. While they do so at their own risk and this is not against the law, it is nevertheless puts them at risk. Hearings such as this will provide individuals who cross the border to buy their drugs with valuable information about the potential dangers involved.

More and more individuals are going on-line to order prescriptions through the mail from foreign countries. How can consumers know whether these products are genuine? Another question that individuals who purchase their prescription from overseas need to consider is how safe is to go on-line and divulge personal information about themselves. There is no way to verify whether the companies selling these products are legitimate. Let the buyer beware is very apt when such buying practices are being conducted.

I wonder if it would be beneficial to have more regulation of these drugs that are flowing into our country through the mail. Counterfeiting of bulk drugs has become one of the most lucrative and also one of the most potentially dangerous issues associated with imported drugs.

These look a like drugs are produced all over the globe and make their way to this country in vast quantities. I have seen these drugs and they appear to be authentic because they look identical to drugs produced by pharmaceuticals made in this country. The packaging looks identical and sadly enough can have detrimental effects because the patients will not be getting the medications they need to treat their illness.

I hope today's hearing will provide us with some answers and perhaps some reassurance that we can stop these dangerous products from entering our country.

PREPARED STATEMENT OF HON. W.J. "BILLY" TAUZIN, CHAIRMAN, COMMITTEE ON
ENERGY AND COMMERCE

Chinese cough medicine filled with poisonous anti-freeze kills 89 children in Haiti. Counterfeit imported anti-seizure drugs suspected of killing several epileptics in the U.S.

Thousands of drugs sold to Americans through the mail from foreign internet pharmacies made in filthy, vermin-infested labs.

Powerful, deadly painkillers declared and brought from Mexico or Canada into the U.S.

People who die or are injured by self-medicating with prescription drugs of unknown quality, unknown dosage levels, unknown impurities, unknown side effects, and unknown interactions.

These are examples of the dangers of many imported pharmaceuticals.

Drum-by-drum, parcel-by-parcel, consumer-by-consumer, imported pharmaceuticals are arriving from unapproved sources, border pharmacies, and even bathtubs or dirty kitchens. Many of these products threaten the public health.

The problem of counterfeit drugs is not just a phenomenon of the developing world. Our lucrative market and ineffective import controls are increasingly making the United States an attractive target for drug counterfeiters and diverters. Last month, three counterfeit prescription drugs were found in the shelves of pharmacies of several states. It is not known whether these fake drugs were made in the United States or overseas. But such a cluster of counterfeits has not been seen for years in this country.

This public health threat of imported pharmaceuticals is getting worse virtually by the day. More Mexican border pharmacies. More foreign internet pharmacies. More drugs in the international mail. More pharmaceutical ingredients from overseas. More people in desperate straits who seek cheaper medicines from abroad. More hucksters, criminals, snake-oil salesmen, slick-willies, and con artists who prey upon consumers, distributors, and manufacturers.

Meanwhile, our federal agencies responsible for keeping out dangerous drugs are no longer maintaining the pretense that the problem can be controlled. For example,

in its December 2000 Performance Plan Summary, the Food and Drug Administration stated: "The Agency is unable to assure the U.S. public that it can prevent unsafe imports from entering the country." The data from a recent joint project between the FDA and the U.S. Customs Service show only a small fraction of drugs in the mail ever gets examined by the FDA and even a visual examination of these products cannot detect the full extent of counterfeit or substandard product. On one side, the FDA and the Customs Service are overwhelmed by a flood of commercial shipments of imported bulk ingredients. On the other, these agencies are confronted by thousands of individuals with personal imports, an army of ants overrunning the system.

Unless we find new effective solutions soon, I believe it is only a matter of time that these uncontrolled imported drugs will lead to an epidemic here that will kill, maim or severely sicken people. Fortunately, this hearing is an important start in reaching solutions. In so doing, we won't lose sight of the real-life problems seniors and other Americans are facing with high drug prices. I know many Americans are resorting to getting what they believe—or have been told to believe—are cheaper versions of U.S. drugs in Canada and Mexico. In many cases, these foreign drugs are not cheaper and they are not the same as U.S. drugs. But the problem of high drug prices and prescription drug coverage is one that we will deal with directly in this Committee. While we tackle affordability, we will pursue safety solutions that target the greatest health risks, and at the same time, minimize disruption and risks for those who feel they must avail themselves of pharmaceuticals in Canada and Mexico.

I congratulate the Subcommittee Chair, Congressman Jim Greenwood, for this essential hearing. He has invited an impressive array of expert witnesses to assess the issues and to discuss proposals and recommendations. I look forward to hearing the testimony, examining the evidence, and getting some answers.

PREPARED STATEMENT OF HON. BOBBY L. RUSH, A REPRESENTATIVE IN CONGRESS
FROM THE STATE OF ILLINOIS

Mr. Chairman, thank you for holding this important hearing on the importation of drugs. More than ever before, Americans rely on drugs to treat chronic health conditions, protect themselves from disease and improve the quality of their lives. Whether the illness be high blood pressure, diabetes or cholesterol, pharmaceuticals allow many to enjoy a better quality of life. Some of the safety concerns surrounding the issue of imported drugs could potentially undermine this ability.

A New York Times article from April of this year reported that American law enforcement officials have estimated the percentage of counterfeit and substandard imported drugs could be as high as 25 percent of the imports. In the past two years, this Committee has investigated the FDA's oversight of counterfeit foreign bulk drugs and uncovered a severe failure by FDA to identify and pursue counterfeit drug makers and distributors, despite internal FDA documents highlighting the dangers posed by specific imported medicines.

We must continue to ensure that Americans have access to safe drugs and I look forward to hearing from the witnesses as to what we can do.

Mr. GREENWOOD. For the benefit of the witnesses, the bells that you just heard indicate that we have a vote on the floor.

And since we would all like to be here for your testimony, the committee will recess for 15 minutes, and reconvene at 11 o'clock.

[Brief recess.]

Mr. GREENWOOD. The committee will reconvene. Without objection, a statement from U.S. Representative Gil Gutknecht will be entered into the record, and hearing no objection, it is so ordered.

[The prepared statement of Hon. Gil Gutknecht follows:]

PREPARED STATEMENT OF HON. GIL GUTKNECHT, A REPRESENTATIVE IN CONGRESS
FROM THE STATE OF MINNESOTA

Mr. Chairman, as a Member of Congress long concerned with our Nation's policy regarding imported pharmaceuticals, and who authored legislation regarding mail order imports signed into law just a few months ago (PL 106-948, § 746), I appreciate this opportunity to offer my opinion about the direction our drug import policy should take. I have a long-term vision for what our wholesale importation policy should be, but today I want to address the narrower subject of this hearing: govern-

ment treatment of prescription drugs mail-ordered from another country for personal use. My point is simple. The FDA's personal use importation policy is currently fatally flawed, as it favors the most dangerous, unapproved drugs, while disfavoring commonly prescribed, FDA-approved drugs that can be safely imported for personal use.

I learned about this issue several years ago, when some of my constituents—who would soon be joined by thousands of Americans—traveled to Canada on buses to buy commonly-prescribed, FDA-approved drugs available at about half the price for which those same drugs are sold in the United States. These constituents' faced no difficulty at the border importing their Coumadin, Prilosec, and Lipitor—commonly prescribed, FDA-approved drugs. However, when they tried to reorder those same drugs through the mail, the FDA stopped the packages, opened them, and enclosed warning letters saying the drugs appeared to be illegal and might be confiscated if they were imported again.

Needless to say those constituents were confused by the FDA's disparate treatment of the same product—easy admission on the bus at the border, strict warnings in the mail. As it turns out, my constituents had encountered what is only one of the many inconsistencies and, indeed, flaws in the FDA's personal use importation policy—a patchwork quilt of written and unwritten rules that finds no basis in statute. Because I've explained these flaws in detail in a letter to the Secretary of Health and Human Services, Tommy Thompson, I will only briefly outline them here and request that my letter to the Secretary be entered into the Record.

The first problem with the FDA's personal use policy today is that it favors unapproved drugs over approved drugs. In the early 1990s, the FDA evolved a "compassionate use" policy regarding importation of prescription drugs. This policy allowed individuals seeking medical treatments not available in this country to bring unapproved drugs into the United States for their personal use. However, in the last few years, this policy has evolved into the FDA's current, unwritten, "personal use" policy. Under this policy, the FDA allows individuals to bring up to a three-month supply of drugs into the United States *on their person*, whether the drugs are approved for use in the United States or not. My constituents took advantage of this policy when they brought lower-cost drugs back into the United States by bus.

Thus, the FDA's written policy expressly allows imports of *unapproved*, experimental drugs, but disallows imports of FDA-approved drugs. This doesn't make any sense. As I wrote to Secretary Thompson, "While I certainly agree that the very sick should have formal access to unapproved products, it makes no sense...that the very poor should not have formal access to approved products."

The second problem with the FDA's personal use policy is that it favors drugs carried across the border to drugs mailed across the border. As my constituents found out, the FDA currently allows drugs to be carried across the border that it disallows when they appear at the border in the mail. This, too, makes no sense. Why should the FDA allow an individual to carry a drug into the United States on their person, but stop that individual from refilling the very same prescription from the same pharmacy through the mail? I have yet to hear a compelling answer to this question.

But perhaps what is most interesting, and disturbing, about the FDA's complex array of written and unwritten drug importation rules is that *none* of them has a basis in statute. The FDA has used its discretionary authority to create an ad hoc drug importation system that favors the most dangerous products while stopping the safest. To put it in Biblical terms, the FDA's policy strains out a gnat, but swallows a camel. When I have raised this point with the FDA, the Agency claims that all importation of prescription drugs—experimental or FDA-approved—is technically illegal. I'm not convinced this is the case. But even if it is, the question remains: if the FDA can make up an importation system out of whole cloth, shouldn't such a system make sense? If the FDA can use its discretion to allow Americans to carry experimental and FDA-approved drugs into the United States, shouldn't the Agency be able to use that same discretion to allow Americans to mail-order commonly-prescribed, FDA-approved drugs from countries like Canada? Our goal, as I told Secretary Thompson, should be "a clear and logical, written regulatory program that allows consumers access to imported, U.S.-approved drugs" while stopping dangerous, unapproved medicines imported without a prescription.

Supporters of prescription drug importation are often criticized for jeopardizing patient safety. However, we must remember to balance legitimate safety concerns with very real safety concerns for seniors who cannot afford high American drug prices. Often living on fixed incomes, it is not unusual for seniors to break pills in half to make their prescriptions stretch further. At the least, taking the wrong dosages detracts from a drug's desired effect. In addition, I believe what safety concerns do exist might be solved by simply re-allocating the FDA's current border enforce-

ment resources. At present, the FDA appears to be focusing its staff resources on the wrong borders, intercepting what are almost certainly the safest drug packages. According to the FDA's website, this year the FDA has stopped and detained 18 times more packages coming from Canada (54) than from Mexico (3). Last year, the FDA stopped 90 packages coming from Canada and only one from Mexico. This is inexplicable, particularly given the FDA's testimony today concerning dangerous medicines entering the United States through Los Angeles.

In conclusion, the FDA must certainly address legitimate safety concerns in its approach to mail ordered prescription drugs. However, such concerns should not discourage the Agency from overhauling what has become a confusing, contradictory array of written and unwritten policies that prevent importation of safe, FDA-approved products. At the end of the day, the FDA should not be standing between the American consumers and safe, lower-cost prescription drugs.

I thank the Chairman again for the opportunity to contribute to this discussion.

CONGRESS OF THE UNITED STATES
HOUSE OF REPRESENTATIVES
May 2, 2001

The Honorable TOMMY G. THOMPSON
Secretary of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

DEAR TOMMY: When you visited the House Budget Committee recently, I mentioned my concern that the Food and Drug Administration (FDA) is inappropriately interfering with mail order shipments of prescription drugs from Canada for the personal use of Americans. I have looked into this matter further, and I find that not only is the FDA acting in violation of a new law requiring due process for mail order importers, but the Agency's entire policy regarding personal use importation is deeply flawed and inconsistently applied. I write to ask you to give both problems your prompt attention.

Personal Use Policy

In the 1990s, the FDA evolved a *written* policy allowing individuals seeking medical treatments not available in this country to bring drugs not approved for use in the United States for their personal, "compassionate use." Additionally, the FDA allowed licensed practitioners in the United States to prescribe for their patients drugs approved in a foreign country but not in the United States. In the last few years, this sensible compassionate use policy has further evolved into the current, *unwritten* "personal use" policy. Under the personal use policy, the Agency allows individuals to bring up to a three-month supply of drugs into the United States, whether the drugs are approved for use in this country or not.

This combination written/unwritten personal use policy is flawed for a number of reasons.

First, it favors unapproved drugs over approved drugs. Written FDA policy explicitly allows foreign, unapproved drugs into the United States (Regulatory Procedures Manual, Chapter 9). Yet that same written policy explicitly rejects importation of products available domestically. While I certainly agree that the very sick should have formal access to *unapproved* products, it makes no sense to me that the very poor should not have formal access to *approved* products. When I've proposed extending the written "compassionate use" policy to medications available in the United States, the FDA has responded that such imports are technically illegal. While I am not convinced this is the case, this argument, if true, would also destroy FDA's written personal use exemption for unapproved drugs as well, as, according to the FDA, that policy finds no basis in the law either. *My point is this: if FDA can compassionately use its discretion to allow, in writing, experimental, unapproved drugs into the United States, it surely ought to be able to use its discretion to allow, in writing, common, FDA-approved medications into the United States—given the FDA's position that both types of imports are technically illegal.*

Second, the FDA's unwritten personal use policy favors drugs carried across the border to drugs mailed across the border. This is yet another layer of discrimination and inconsistency in the FDA's drug importation policy. Under current FDA practice—which is what the unwritten personal use policy amounts to—Americans are freely allowed to carry common, FDA-approved drugs across the border on their person. Yet, when the same individuals have tried to refill the same prescriptions through the mail, the FDA has stopped the packages, opened them, and sent importers threatening warning letters. (As you know, this egregious aspect of the FDA's unwritten personal use policy prompted me to write the Drug Import Fair-

ness Act, which requires due process to mail order importers. Unfortunately the FDA is violating the letter and spirit of this law. I discuss this matter further, below.) When approached on this disparate and illogical treatment of mail orders, the FDA responds that all imports of FDA-approved drugs are technically illegal. Again, while I am not convinced this is the case, this argument, if true, would also destroy the FDA's unwritten policy of allowing FDA-approved drugs to be carried across the border. *That is, if FDA can use its discretion to allow approved drugs into the United States if carried across the border, it surely ought to be able to use its discretion to allow approved drugs if mailed across the border—given, again, the FDA's position that both types of imports are technically illegal.*

In light of these flaws and inconsistencies, which only benefit Americans wealthy enough to travel abroad, I am requesting that your Department oversee an immediate revision of FDA's personal use policy. Our goal should be a clear and logical, written regulatory program that allows consumers access to imported U.S.-approved drugs, whether those consumers live in San Diego or Kenosha. Given the FDA's apparently broad discretion in these matters, why not have a policy that makes sense for all Americans? I would love to sit down with you to discuss how this might work.

Warning Letters

Another reason I believe the FDA's personal use policy is fatally flawed is the immense difficulty I have had forcing the Agency to give mail order importers a simple explanation of what the FDA believes the importers are doing wrong. I mentioned earlier the Drug Import Fairness Act, which required the FDA to give mail order importers due process. Simply put, the law directs the FDA to advise mail order importers, in detail, why the particular import appeared to violate the law.

The FDA has defied this law and is now holding up mail order shipments from Canada and sending intimidating detention letters to American consumers stating that the drugs, such as Lipitor, appear to be *unapproved* and misbranded and therefore are refused admission—and may be destroyed. While the letters state that the consumer is not being accused of breaking the law, they state that the package appears to be unapproved and they threaten the consumer that future shipments may be denied entry thus sounding very much like the warning letters the FDA was sending before. (Indeed, under the definitions section of the Drug Import Fairness Act, these letters are, in fact, warning letters.)

But what's most disturbing about the new letters is that, while some of them cite which section of the law the packages appear to violate (the Drug Import Fairness Act requires this of all such letters), the letters do not give reasons, based on the facts of the particular package, for making that determination. This is a patent violation of the Drug Import Fairness Act (section 746(g)(1)(C)). It also violates long-established case law (*L&M Industries v. Kenter*, 458 F.2d 968, 970-71 (2nd Cir. 1972)).

I request that your Department examine the FDA's current policy regarding letters to individuals mail ordering prescription drugs. Specifically, I would like to know what the Agency will be doing to fully comply with the Drug Import Fairness Act's requirement that such letters "state the reasons underlying the [FDA's]" decision that an import appears to be unapproved—including an explanation of the facts involved in each specific imported package.

Our own FDA should not stand between sick seniors, living on fixed incomes, and lower drug prices. Basic fairness won't tolerate it. And neither will the Congress.

Thank you for your attention to both of these important matters.

Sincerely,

GIL GUTKNECHT
Member of Congress

Mr. GREENWOOD. The Chair welcomes our first witnesses, the Reverend and Mrs. Edwin Rode. We thank you very much for coming to Washington, and we thank you very much for your patience.

As I explained to you last night, you have to listen to us first, and then we will listen to you. We are very pleased that you have joined us. As we mentioned to you last night, you are aware that the committee is holding an investigative hearing, and in doing so, we have had the practice of taking testimony under oath.

Do either of you have any objections to testifying under oath? Seeing that you do not, the Chair also advises you that under the rules of the committee that you are entitled to be advised by counsel. Do you desire to be advised by counsel during your testimony?

Mr. RODE. No.

Mr. GREENWOOD. Seeing your response in the negative, would you please rise then and raise your right hand, and will swear you in.

[Witnesses sworn.]

Mr. GREENWOOD. You are now under oath, and you may give your testimony. You are recognized for 5 minutes, but you may testify for as long as you care to. Thank you.

TESTIMONY OF REV. EDWIN AND HELEN RODE

Mrs. RODE. Good morning, Chairman Greenwood, and good morning to the rest of the committee. My name is Helen Rode, and this is my husband, Ed Rode. We are grateful for the opportunity to speak before this committee to share what has happened to our family.

Our son, Todd, was found dead in his apartment on November 16, 1999. We are convinced that his death was caused by drugs that he obtained from a foreign country through the Internet. I would like to tell you a little bit about our family. Todd's death has changed the lives of all of us.

My husband is a retired United Methodist pastor. I am a wife, a mother, and a homemaker. We moved from the Chicago area to Athens, Georgia in 1992 when we retired.

Our daughter, Lisa, is a registered nurse. She and her husband, Kevin, live in a suburb of Chicago with their children, Nathan, Neal, and Claire. Our younger son, Curt, lives in Knoxville and teaches in the English Department at the University of Tennessee.

Todd was our middle child. Until the age of 15, he was a high achieving child, interested in music and sports. In high school, he began exhibiting the behavior of teenage depression syndrome. He battled this illness the rest of his life.

Todd had the heart and soul of a musician and wanted to make this his major in college. However, he was drawn to the field of psychology and counseling. He graduated magna cum laude with a major in psychology and a minor in music. The faculty named him the outstanding senior in the Psychology Department.

Todd worked for several years as a counselor with young people in a hospital setting. Discovering that this was not good for his own mental health, he took a post-graduate course at DePaul University in Chicago to become a computer programmer.

He worked in this field for a number of years, constantly fighting bouts of depression and anxiety. Periodically, he would check himself into the hospital, but become anxious about insurance coverage and check himself out.

At the time of his death, Todd was on disability leave and losing his job and health insurance. During this time he was under the care of a psychiatrist and counselor at a mental health facility in Chicago.

In October 1999, when no one in the family could reach Todd by phone or E-mail, we became seriously alarmed. We assumed that he had checked himself into a hospital without telling us, or was too sick to be in communication with anyone.

My husband called the Chicago Police Department on November 16, 1999 and they, along with his sister, went into Todd's apart-

ment and discovered that he had died. When our daughter went to his apartment, she gathered all the medications she could find.

It was at this time that we learned that Todd had ordered controlled drugs from a pharmacy and doctor in another country. In going through Todd's records, we could trace the Internet source, the medications ordered, the date they were ordered, and how he paid for them.

These drugs were Venlafaxine, Propoxyphene, and Codeine. All of these drugs are controlled substances, which were secured from an overseas pharmacy without any safeguards. The report of Chicago's Medical Examiner and Coroner stated that Todd's death was due to an accidental massive overdose of these drugs.

After a few weeks of numbing grief, I began to feel intense anger that someone as ill as our son could be tempted to obtain medication that required nothing but filling out a questionnaire on the Internet.

We tried to channel that anger into action. We sent a letter to every elected official and agency that we could think of. We were pleased that we received replies from most of these letters.

Agents from the FDA and Customs Departments in Atlanta came to our home in Athens on two different occasions. We gave copies of all our information to them. Sometime later, they contacted their counterparts in Chicago, who then visited our daughter and took from her the medications that Todd had received from the foreign pharmacy.

This all happened a number of months ago, and we had heard nothing more until a counsel from Chairman Greenwood's committee called us. He told us about this hearing concerning Internet use to order drugs from foreign countries.

We then sent to him all of our information regarding Todd's use of the Internet to obtain these drugs. It was then asked by this counsel if we would be willing to speak to this panel and tell our story. We agreed to do this, knowing that other very ill people and their families are suffering and grieving like we are.

This grief extends beyond our immediate family. Todd's aunts, uncles, cousins, friends, nephews and niece have felt Todd's death very deeply. Todd will never hear Nathan play saxophone in the middle school jazz band. He will not see Neal's skills playing first base. He will never read Clare's or Curt's poetry.

He will not grow into middle and old age with his brother and sister. And, we, his parents, have lost a child of our hearts. We are left to grieve, not only for the struggles that he constantly faced in his life, but also the horrifying circumstances of his death.

Our plea to you is to do whatever is possible to enact legislation and allocate funds to the appropriate agencies to control and eliminate this dangerous use of the Internet. We want to thank you for permission to tell our story before this committee.

[The prepared statement of Helen Rode follows:]

PREPARED STATEMENT OF HELEN RODE

Good Morning.

My name is Helen Rode. This is my husband Ed Rode.

We are grateful for this opportunity to speak before this Committee—to share what has happened to our family. Our son, Todd, was found dead in his apartment

on November 16th of 1999. We are convinced that his death was caused by drugs that he obtained from a foreign country through the internet.

I would like to tell you a little bit about our family. Todd's death has changed the lives of all of us.

My husband is a retired United Methodist pastor. I am a wife, a mother, and homemaker. We moved from the Chicago area to Athens, GA in 1992 when we retired.

Our daughter, Lisa, is a registered nurse. She and her husband, Kevin, live in a suburb of Chicago with their children, Nathan, Neal, and Claire.

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At the time of his death, Todd was on disability leave and losing his job and health insurance. During this time he was under the care of a psychiatrist and counselor at a Mental Health facility in Chicago.

In October of 1999, when no one in the family could reach Todd by phone or Email, we became seriously alarmed.

We assumed that he had checked himself into a hospital without telling us or was too sick to be in communication with anyone.

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In going through Todd's records we could trace the internet source, the medications ordered, the date they were ordered and how he paid for them. These drugs were Venlafaxine, Propoxyphene, and Codeine. All of these drugs are controlled substances which were secured from an overseas pharmacy without any safeguards.

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This all happened a number of months ago, and we had heard nothing more until a counsel from Chairman Greenwood's committee called us. He told us about this hearing concerning Internet use to order drugs from foreign countries. We then sent to him all of our information regarding Todd's use of the Internet to obtain drugs from a foreign country. It was then asked by this counsel if we would be willing to speak to this panel and tell our story. We agreed to do this, knowing that other very ill people and their families are suffering and grieving like we are.

This grief extends beyond our immediate family. Todd's aunts, uncles, cousins, friends, nephews and niece have felt Todd's death very deeply.

Todd will never hear Nathan play saxophone in the middle school jazz band. He will not see Neal's skills playing first base in baseball. He will never read Claire's or Curt's poetry.

He will not grow into middle and old age with his brother and sister. And, we, his parents have lost a child of our hearts. We are left to grieve, not only for the

struggles he constantly faced in his life, but, also, the horrifying circumstances of his death.

Our plea to you is to do whatever is possible to enact legislation and allocate funds to the appropriate agencies to control and eliminate Internet access to drugs.

We want to thank you for permission to tell our story before this committee.

Mr. GREENWOOD. Thank you, Mrs. Rode, for your testimony. We know how difficult this is for both of you. We are indeed sorry for your loss. Your son had prescriptions, or is it correct that your son had prescriptions at one point? Both of you can share that microphone and either one of you can respond to the questions.

Mrs. RODE. All right.

Mr. GREENWOOD. Is it the case that your son at one point in the course of his psychiatric care had prescriptions for certain drugs; is that correct?

Mr. RODE. Yes, sir, that's true.

Mr. GREENWOOD. Do you know what they were?

Mr. RODE. At this point, I do not. Todd was very secretive about that. He kept a lot of this information to himself. I think he was embarrassed by his sickness, and at that point was a very private person.

Mr. GREENWOOD. So you are not sure if he had prescriptions prior to this for drugs?

Mr. RODE. I was sure that he did, yes, because he was under psychiatric care.

Mr. GREENWOOD. So you assume so, although I understand from talking to you last night that for reasons of confidentiality the psychiatrist is not willing to share or not able to share that information?

Mr. RODE. Well, we have of course talked to the—not to the psychiatrist, but talked to the office of the psychiatrist, and we never did talk to the psychiatrist. And we were told at that time that we were not by law permitted to get the information that we requested.

That the only people that could get that information was the FDA and a subpoena.

Mr. GREENWOOD. Okay. But he certainly had no prescriptions for the drugs that he obtained?

Mr. RODE. That's correct. That is absolutely correct.

Mrs. GREENWOOD. And he did not use a prescription to obtain those drugs. And how many different drugs were found in his body?

Mr. RODE. Three.

Mr. GREENWOOD. So Todd purchased three drugs and there was no one able to monitor whether he should be taking any or all of those drug?

Mr. RODE. That is correct, sir.

Mr. GREENWOOD. And no doctor, no psychiatrist, no pharmacist to monitor that, let alone to describe to him the interactions and the dangers of taking those drugs in certain dosages.

And I would assume that we don't know yet whether the dosage, the actual dosage of the pills that he was taking, was equal to what was written on the label; is that right?

Mr. RODE. I think that is correct. Todd was pretty astute with understanding drugs, but I think that we—we assume that the drugs that he received from overseas were probably heavier dosages, and were not his proper dosage, even though on the informa-

tion that we received, in which the comptroller for this particular group has—there was a dosage listed, but whether it was the actual dosage that he received, we are not sure of.

Mr. GREENWOOD. Well, from what we have seen, when one orders prescription drugs over the Internet from foreign countries, there is no way of knowing what the drug that is actually ingested contains.

And there is no way of knowing what is in it, or what the dosage is, because the labels are often counterfeit, and the container is counterfeit, and that is of course that we are trying to get at here.

Mr. RODE. This hearing has opened up a new aspect to us of the whole problem.

Mr. GREENWOOD. Right. Now, all of this information was shared with the Food and Drug Administration how long ago?

Mrs. RODE. I am not sure when they first came to our house. We sent our letter out to these agencies in July of last year, and within a few weeks, I think we heard. I am not really sure when they first contacted us.

Mr. GREENWOOD. Have they given you any indication to date as to where their investigation has led them?

Mrs. RODE. No, we do not know that.

Mr. RODE. Prior to our coming here, we were in Chicago to visit our daughter, and a person from Customs called and warned us not to give the foreign country name or the pharmacist's name.

Mr. GREENWOOD. Because there is an ongoing criminal investigation—

Mr. RODE. Yes, sir, that is correct.

Mr. GREENWOOD. [continuing] underway, and hopefully we will find the source of the drugs and prosecute the perpetrators if there is evidence of criminal wrongdoing. I would yield back my time and recognize for purposes of inquiry the gentleman from Florida, Mr. Deutsch.

Mr. DEUTSCH. Thank you very much, and again, I know how painful it must be for you to be here, and again thank you for really sharing this with us. I think all of us are hoping that by this hearing, and by our actions, and by your actions, we can at least attempt to make sure that no other parents in America would ever experience what you have experienced.

Do you have any specific suggestions of—I am asking maybe beyond, but any recommendations of what you think Congress should be doing to prevent these kinds of tragedies in the future?

Mrs. RODE. Well, I think that the Oversight Committee—we know nothing about all of this, let me assure you. But I feel that it has to be approached from several different angles.

I think certainly the Legislature needs to be involved with the laws, and see that the laws are carried out. If we need more laws, and then the appropriate agencies, then we need to do what is needed to be done.

Mr. RODE. They need to be funded in order to be able to do the things that are required by the law. It is just a horrendous problem. The Customs man, when he first came out, he said that most of the Customs things came through Memphis, and he said it was just impossible to investigate all of them.

We were kind of surprised that Customs and the FDA came together. They both came together out to visit us twice.

Mr. DEUTSCH. Now, have you heard from any of the parents or any of the relatives of people that this has happened to also?

Mr. RODE. No, sir, we have not; or from Customs or the FDA either.

Mr. DEUTSCH. I thank you, and I yield back the balance of my time.

Mr. GREENWOOD. I recognize Mr. Stupak for questioning.

Mr. STUPAK. Thank you, Mr. Chairman. I am sorry to hear about your loss. Let me just leave it at that. You indicated that your son was taking heavier dosages than what he should have been, and that is what you assumed, correct?

Mr. RODE. No, this is what the coroner and the medical examiner's report told us.

Mr. Stupak. Was it a specific drug then that caused this?

Mr. RODE. We did name the drugs in our presentation.

Mr. STUPAK. Is that drug obtainable in the United States?

Mr. RODE. I am not familiar with drugs, and so I can't answer your question. I'm sorry.

Mr. STUPAK. When we introduced our legislation last year, we asked for simple things like the pharmacist, who is supposed to be—when you go on the Internet, and you order your prescription, there has to be a licensed pharmacist who would display his license and certificate from the State where they are practicing in.

We asked that there be a physical location, where you can know whether it is in Menominee, Michigan, or Chicago, Illinois, or wherever; as opposed to using some bogus address, and you know it is really back in Thailand or China where these drugs are being produced.

And then we put penalties in there if they did not have these two simple requirements; a licensed physician or pharmacist, excuse me, and a physical location. And we were accused of trying to stifle freedom of speech under the Internet, and trying to regulate the Internet.

Do you think that that is asking for too much of these web pharmacy companies to at least display the license of their pharmacist and a physical location so you will at least know where they drugs are coming from?

Mr. RODE. I would hope that that would be essential. I really do.

Mr. STUPAK. I understand that there is some restrictions on what we can say because of an ongoing investigation, but you said something in response to a question from the Chairman about some information that you would like to obtain. And is that information from the FDA? Who is that that you would like to obtain some information from?

Mr. RODE. We were told by the counsel that—in fact, we have a session scheduled with Customs later in the day. We just want to know what is being done. That's all. We have had no knowledge at all, and we have been told nothing as to what is being done. And coming back to your previous question—

Mr. STUPAK. Before you do that, if there are some questions that you need to know after you meet with counsel or the FDA, and they don't tell you, would you let us know? Would you let us know?

Mr. RODE. We will inform you; yes, sir, we will. We want to cooperate in every way we can. That's why we are here.

Mr. STUPAK. This is the Oversight Committee, and we have extra power that we can get some of these things questioned. We are not trying to stifle an investigation, but you certainly have a right to know.

Mr. RODE. I understand.

Mr. STUPAK. You had another question?

Mr. RODE. Well, coming back to your question, I think the Freedom of Information is important, but I think that there are some things that just can't be put out, you know? I think there should be some restrictions.

And I don't feel telling the information that you were suggesting about the Internet and the pharmacy, and the pharmaceutical number or whatever it is, I feel that information should be very vital to helping solve this kind of problem.

Mr. STUPAK. Well, when we started looking at this almost 18 months ago, some of us—there were maybe a dozen or two dozen of these pharmaceutical sites, and when we had our hearing last year, it was like 300 or 400, and now I think we are closer to a thousand.

And we introduced our legislation, and we were told not to worry, and that the Internet community will police ourselves, and we will take care of that. Obviously, they are not, and the number of websites continue to explode. And as I said in my remarks, they are very attractive when you think you are getting a good deal, and you think you are getting the drugs that you want.

But as we have seen, whether it was L.A. or Dulles, it is anything but what you can imagine is coming through, and people are consuming it. They have no idea. You know, we are still searching for a direction.

And we have other cases like yours throughout this country, and it is time that we do something together as a Congress and regulatory agencies in this country. That is what we rely upon them to do for the American public, and to offer that simplest degree of protection, and obviously they are not doing it.

Mr. RODE. Thank you.

Mr. STUPAK. Thank you, Mr. Chairman, and I yield back.

Mr. GREENWOOD. The Chair thanks the gentleman, and recognizes the gentleman from Florida, Mr. Bilirakis.

Mr. BILIRAKIS. Thank you, Mr. Chairman. Reverend and Mrs. Rode, I, too, offer my sympathy. As I was on the elevator, and I don't remember whether it was on the way up or the way back, with Mr. Dingell, the Ranking Democrat, who sat over on the other side, said Mike, we have got to do something about this. Well, yes, I guess we do, but I don't know what. This is the sort of thing that we are going to be looking at over a period of time.

I am curious though. Let me ask you, and forgive me again for bringing up Todd, but if there were warnings, educational statements. For example public service announcements, where the t.v. studios are required to offer so much time.

In other words, if there were warnings out there, would Todd still have gone forward? Forgive me, but is that a difficult question?

Mr. RODE. I think that is a hard question to answer, because Todd's circumstances were that he was chronically depressed, and chronically depressed people don't always make the wisest decisions at certain times. And I think that more needs to be done than just warnings.

Mr. BILIRAKIS. Yes, and I am not disputing that. Maybe there is a lack of education out there, in terms of the concerns. I knew someone going through medical school in Australia, who befriended my family, and I guess somebody said something about a bad stomach, and the next thing I knew, we received this stuff from China in the mail that he made arrangements for.

So, those things take place. Well, you understand. I had a lot of confidence in the gentleman, but I didn't take it. But again I wasn't sure. So I wonder if that might be of some help from an immediate standpoint.

Mr. RODE. I am sure that it will be, but it is not the total answer.

Mr. Bilirakis. No, it is not the total answer. All right. Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman, and recognizes the gentlelady from Colorado for questioning.

Ms. DEGETTE. Thank you, Mr. Chairman. I just echo what everyone else has said, and let me say that part of the frustration that this committee has had is the very nature of the Internet, and how someone can go on a computer, and they find a site that says this is a pharmacy, and order these drugs, and fill out a questionnaire, and unlike a traditional pharmacy, which has a physical location, the Internet doesn't have that.

And so we are really stricken with a very high degree of uncertainty as to what should the laws that we pass say. But having said that, I think you heard in my opening statement and others that some of us are very frustrated that we keep having these hearings, and these drugs keep coming in.

And people like your son are dying, and it seems that there is an approach. Congressman Stupak and others have a bill, and I just want you to know that we intend to redouble our efforts to both enforce existing laws to stop this from coming into the country, and also to pass any new laws that we can.

But I think you have realized, and I think other families like yours need to realize just passing a law banning this on the Internet is not going to immediately stop it, because it is hard to shut down these sites.

Having said that doesn't mean we shouldn't try. And I guess I would just ask you a simple question, which is don't you think that other families like yours, who maybe have not experienced a tragedy yet, knew of the dangers and risks, and knew of the regulatory challenges, they would support any efforts Congress might make both to enforce existing laws and to try to pass new laws?

Mrs. RODE. I certainly think so.

Mr. RODE. I would hope so.

Ms. DEGETTE. And I will yield the balance of my time to Congressman Stupak.

Mr. STUPAK. Thanks for yielding. In your statement here, we have seen the drugs that your son was taking, and all of those

were controlled substances. Therefore, there should have been a prescription. Do you know if with any of those containers there was a prescription for him to receive these drugs?

Mr. RODE. What we picked up in his apartment, counsel has that. So the prescriptions were listed.

Mr. STUPAK. Was there a prescription with the packaging? You see, underneath current law, and I am sure that someone will correct me if I am wrong, but under current law, he could not have even received them unless there was a valid prescription with that package, because you have to have a prescription with it. That's what I am asking.

Mr. RODE. Rephrase this question. I am having a little trouble with it.

Mr. STUPAK. Sure. In order for a drug to be received through the mail in the United States, especially a controlled substance, there has to be a number of requirements if it is going to come through the mail, and that's where he got the drugs, through the mail, right?

Mr. RODE. That is our assumption, yes, sir.

Mr. STUPAK. Okay. One of them is that there has to be a prescription if it is a controlled substance.

Mr. RODE. Well, we did not find anything like that.

Mr. STUPAK. And technically you can't even ship it without a valid prescription and that is what is getting flooded in this country.

Mr. RODE. Well, this is what we were told by Customs.

Mr. Stupak. Okay.

Ms. DEGETTE. I yield back, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentlelady, and recognizes for 5 minutes for inquiry the gentleman, Mr. Whitfield.

Mr. WHITFIELD. Thank you, Mr. Chairman, and thank you all for coming today to help us examine what we might be able to do to alleviate problems like this in the future. I just have a couple of questions.

One, would you repeat for me the drugs that were involved in this instance? I think you were pronouncing them, but I wasn't sure. You said one was codeine?

Mr. RODE. One was codeine.

Mrs. RODE. The drugs that we were mentioned were the ones that were named on the death certificate as being having toxic doses, the ones that I mentioned earlier.

Mr. WHITFIELD. Okay. And do you have the spelling of those?

Mrs. RODE. Yes. I can spell it better than I can pronounce it. It is b-e-n-l-a-f-a-x-i-n-e.

Mr. WHITFIELD. And what was the other?

Mrs. RODE. P-r-o-p-o-x-y-p-h-e-n-e. And the third substance that was found to be toxic was codeine.

Mr. WHITFIELD. Okay. And all of those were listed on Todd's death certificate?

Mrs. RODE. On Todd's death certificate, yes.

Mr. WHITFIELD. And how old was Todd?

Mrs. RODE. Thirty-eight.

Mr. WHITFIELD. Okay. And you know from which country this came, but you have been requested not to talk about it?

Mr. RODE. That is correct.

Mrs. RODE. All this information has been given though to the agencies.

Mr. WHITFIELD. Okay. And I think they will be here today, and so I will yield back the balance of my time, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman for his information. The common names of two of those drugs are Darvon and Zanax. The Chair recognizes for inquiry for 5 minutes the gentleman from Oklahoma, Mr. Largent.

The gentleman passes. Mr. Bass. The gentleman passes. In that case, we have completed our inquiry. Again, Reverend and Mrs. Rode, thank you so very much for coming to Washington to testify, and you can be assured that this committee is going to work very, very hard to come up with a solution so that this doesn't happen to the parents of other Americans. Thank you very much for coming.

Mrs. RODE. Thank you very much.

Mr. RODE. We appreciate all you have done, sir.

Mr. GREENWOOD. You are excused. The Chair then calls forward the second panel, Dr. Donald Vereen, Office of the National Drug Control Policy; Ms. Laura Nagel, of the Drug Enforcement Administration; Mr. William Hubbard of the Food and Drug Administration; Ms. Elizabeth Durant, of the U.S. Customs Service; Dr. Alan I. Leshner, Director of the National Institute on Drug Abuse; and Landon Gibbs, First Sergeant, of the Virginia State Police. Will you please come forward and be seated.

I thank the witnesses for their presence. You are aware that the committee is holding an investigative hearing, and when doing so, we have had the practice of taking testimony under oath. Do any of you have objections to testifying under oath?

Seeing no objections, the Chair then advises you that under the rules of the House, and of the committee, you are entitled to be advised by counsel. Do you desire to be advised by counsel during your testimony?

Seeing no such interest, the Chair asks if you please rise and raise our right hand, and I will swear you in.

[Witnesses sworn.]

Mr. GREENWOOD. Please be seated, and you are now under oath. And we will recognize first for testimony Dr. Vereen. Thank you, sir. You are recognized for 5 minutes.

TESTIMONY OF DONALD R. VEREEN, JR., DEPUTY DIRECTOR, OFFICE OF NATIONAL DRUG CONTROL POLICY; LAURA M. NAGEL, DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMINISTRATION; ELIZABETH G. DURANT, EXECUTIVE DIRECTOR OF TRADE PROGRAMS, U.S. CUSTOMS SERVICE; WILLIAM K. HUBBARD, SENIOR ASSOCIATE COMMISSIONER FOR POLICY, PLANNING AND LEGISLATION, FOOD AND DRUG ADMINISTRATION; ALAN I. LESHNER, DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE; AND LANDON S. GIBBS, FIRST SERGEANT, VIRGINIA STATE POLICE

Mr. VEREEN. Good morning. Chairman Greenwood, Ranking Member Deutsch, and distinguished members of the subcommittee,

my name is Dr. Donald Vereen, and I have the distinct honor of coming before the subcommittee today as the Deputy Director of the Office of National Drug Control Policy.

First, as the father of two children, I want to extend my heartfelt condolences to Reverend and Mrs. Edwin Rode on the loss of their son, Todd. Drug prevention, education, and treatment for youth and adults must remain the heart and soul of our counter-drug efforts in the Federal, State, and local levels of drug control.

On May 10, President Bush stated that the most effective way to reduce the supply of drugs in America is to reduce the demand for drugs in America. Therefore, this administration will focus unprecedented attention on the demand side of this problem. We recognize that the most important work to reduce drug use is done in America's living rooms and classrooms, churches, synagogues, mosques, the work place, and in our neighborhoods.

ONDCP is committed to continuing to improve our drug prevention efforts to avoid such tragedies in the future. I want to thank the subcommittee for the opportunity to testify on the subject of personal importation of controlled substances.

ONDCP greatly appreciates your continuing interest in this public health and safety issues associated with the importation of pharmaceuticals. I realize that my time is limited, and I will keep my opening remarks brief, and focused on ONDCP's coordinating role in this issue. I respectfully request that the subcommittee enter my written statement into the record.

Mr. GREENWOOD. That will be done, sir.

Mr. VEREEN. ONDCP recently began to assist in coordinating a response to the challenges posed by the personal importation of controlled substances across the land border of the United States.

Although ONDCP is well suited to provide assistance on issues transcending the jurisdictional boundaries of several departments and agencies, we recognize the institutional expertise that resides in other agencies that are represented here today.

The DEA, the FDA, the Customs Service, and NIDA, the National Institute on Drug Abuse, are working closely together to ensure that citizens of our country can continue to rely on the guidelines established for using controlled substances in a manner that maximizes health, safety, and efficacy.

The solution to these challenges is complex. We must consider the interaction among a variety of statutes, regulations, enforcement practices, research, and citizen awareness.

Let me be clear that despite the challenges, the DEA and FDA have assured us that they will continue to provide the U.S. Customs Service with the guidance that they require to carry out their mission relating to the importation of pharmaceuticals effectively, and with limited inconvenience to licit commerce and personal travel.

Since becoming involved in assisting and coordinating a U.S. response to the personal importation of personal-use pharmaceuticals, and in particular controlled substances, ONDCP last month convened four separate meetings with the DEA, FDA, U.S. Customs Service, and NIDA.

We have made substantial progress, and I believe that we are moving forward toward forms of resolution. We know that there is

some diversion of legally produced pharmaceutical controlled substances in the U.S., and that drug users and traffickers also obtain these controlled substances from other places. For example, Mexican pharmacies.

Both the U.S. and Mexican governments understand the issues and will continue to work together to address them. In fact, the DEA has two diversion investigators assigned to Mexico City—where they are responsible for coordinating bilateral regulatory efforts in any investigations of this sort of diversion.

Turning to the science, we are fortunate to have NIDA providing the scientific basis for our policies. In fact, I would like to commend NIDA for the major initiative that it recently launched on prescription drug abuse and misuse.

Unfortunately, there are a number of factors that indicate prescription drug use and abuse are increasing. I will give an illustrative example of this research, and I am certain that Dr. Leshner will address this issue more completely in his remarks.

In 1999, more than 9 million Americans, age 12 and older, reported past year use of prescription drugs for non-medical reasons.

That is from the National Household Survey from SAMHSA at HHS. Of these 9 million people, one-quarter or more misused prescription drugs for the first time the year prior to the survey.

Furthermore, of these 9 million people, an estimated 4 million reported using prescription drugs for non-medical purposes in the month prior to the survey. So, in conclusion, developing policy and implementing procedures to manage effectively the use and movement of controlled substances requires a holistic, long-term, and research-based approach.

ONDCP is confident that the agencies involved will continue to make steady and significant progress on all of those fronts. Mr. Chairman, I am pleased to answer any questions at this time, or whenever it is appropriate.

[The prepared statement of Donald R. Vereen follows:]

PREPARED STATEMENT OF DONALD R. VEREEN, JR., DEPUTY DIRECTOR, OFFICE OF
NATIONAL DRUG CONTROL POLICY

INTRODUCTION

On behalf of the Office of National Drug Control Policy (ONDCP), I want to thank the Subcommittee for the opportunity to testify before you on the subject of personal importation of controlled substances. Chairman Greenwood, Ranking Member Deutsch, distinguished members of the Subcommittee, we greatly appreciate your continuing interest in the public health and safety issues associated with the importation of pharmaceuticals. The critical oversight of this Subcommittee assists ONDCP in its coordinating role in ensuring continuity and consistency in the Executive Department and agency efforts to provide a comprehensive response to the issue of personal importation and potential diversion of controlled substances. This comprehensive response is essential to our success in reducing drug use and its consequences in our nation. We know that there is no single solution that can effectively address this multifaceted challenge. Drug use prevention, treatment, and research; as well as law enforcement, protection of our borders, drug interdiction, and international cooperation remain necessary components of our efforts.

COORDINATION ISSUES SURROUNDING THE PERSONAL IMPORTATION OF CONTROLLED
SUBSTANCES

As the Subcommittee is aware, ONDCP is a unique organization within the Executive Office of the President that has the dual mission of serving as the President's primary Executive Branch support for counter-drug policy and program oversight while managing several diverse programmatic responsibilities. ONDCP's policy role

consists primarily of developing national drug control policy, developing drug control budget priorities, coordinating and overseeing the implementation of that policy, and evaluating drug control programs to ensure that federal departments and agencies remain focused and coordinated for maximum efficiency and effectiveness.

ONDCP was recently asked to assist in coordinating a response to the challenges posed by the personal importation of controlled substances across the land border of the United States. ONDCP is particularly well-suited to provide such assistance, as this issue transcends the typical jurisdictional boundaries of one department or agency. However, ONDCP recognizes the great institutional expertise that resides in the other agencies represented today. ONDCP takes great pride in the fact that the Drug Enforcement Administration (DEA), the Food and Drug Administration (FDA), the United States Customs Service (USCS), and the National Institute on Drug Abuse (NIDA) are working closely together to ensure the citizens of our country can continue to rely on the guidelines established for using controlled substances in a manner that maximizes health, safety, and efficacy.

ONDCP is committed to supporting our inter-agency counterparts in their efforts to implement a system with respect to the import of controlled substances that draws the appropriate balances among the need to prevent diversion, promote public health and safety by permitting travelers to have the pharmaceutical controlled substances they need, and the need for straightforward standards for Customs to apply at our busy ports of entry. Clearly, the solution to these challenges, is complex; it involves a variety of statutes, regulations, enforcement practices, research, and citizen awareness. As with any complex, multi-jurisdictional solution to a public health and safety issue, the perfect solution will not be conceived, or implemented overnight. There is no silver bullet approach; all affected departments and agencies must bring their own expertise and authorities to bear if we are to succeed. Recognizing that ONDCP only recently became involved in this coordination, the DEA and FDA have advised us that they will continue to provide the USCS with the guidance they require to carry out their mission relating to the importation of pharmaceuticals effectively and with limited inconvenience to licit commerce and personal travel. Clear guidance is essential if we expect Customs officials to continue their efforts, which typically process 1.3 million passengers and nearly 350,000 vehicles at ports and border crossings across the United States each and every day of the year.

The cross-border diversion of pharmaceutical controlled substances obviously has an international component. Some diversion of foreign produced pharmaceutical controlled substances involves U.S. drug users or traffickers who obtain controlled substance pharmaceuticals, including Rohypnol and OxyContin, from Mexican pharmacies. The U.S. government highlighted the need to better control the movement of prescription drugs during the April 2-3, 2001, U.S./Mexico Senior Law Enforcement Plenary. The Mexican government understands the issues and agreed to address them, although they have not yet presented a specific course of action. We will continue to follow-up with them. DEA has two diversion investigators assigned to Mexico City where they are responsible for coordinating bilateral regulatory efforts and any investigations of this sort of diversion.

We cannot forget that the basis for our involvement is preserving the safety of our citizens. In order to maintain credibility with those we seek to protect, the approaches we employ must be rational and research-based. We are fortunate to have NIDA providing the scientific basis for our policies. In fact, I would like to commend NIDA for the major initiative it recently launched on prescription drug abuse and misuse, resulting in a Research Report on *Prescription Drugs Abuse and Addiction*. NIDA should also be recognized for its ability to translate its findings into clear, concise messages which it disseminates to professionals and the general public alike.

Unfortunately, there are a number of factors that indicate prescription drug use and abuse are increasing:

- In 1999, more than nine million Americans aged 12 and older reported past year use of prescription drugs for non-medical reasons. (National Household Survey on Drug Abuse)
- Of those nine million people, one quarter or more misused prescription drugs for the first time the year prior to the survey.
- Furthermore, of those nine million people, an estimated 4 million reported using prescription drugs for non-medical purposes in the month prior to the survey.
- NIDA's Community Epidemiology Work Group which monitors 21 major U.S. metropolitan areas for community-level drug use and abuse trends, also reports a general increase in abuse of selected prescription drugs in several cities in recent years.

CONCLUSION

Developing policy and implementing programs and procedures to manage effectively the use and movement of controlled substances requires a holistic, long-term, and research-based approach. While we cannot expect to resolve these challenges overnight, we can and will continue to make steady and significant progress on all fronts. Since becoming involved in this issue, ONDCP has convened several inter-agency meetings to identify the myriad of issues involved in maximizing the effectiveness of our policy concerning the personal importation of controlled substances across the U.S. land borders. ONDCP will remain an active participant in the decision-making and implementation processes.

We look to this Subcommittee, and indeed the entire Congress, to continue providing bipartisan leadership in this effort. ONDCP is committed to working within the Executive Branch, as well as with Congress, state and local governments, international participants, and private citizens to reduce drug use and its consequences in our nation.

Mr. GREENWOOD. The Chair thanks the gentleman and we will hear from each of our witnesses, and then begin the questioning.
Ms. Nagel.

TESTIMONY OF LAURA M. NAGEL

Ms. NAGEL. Chairman Greenwood, Ranking Member Deutsch, and other members of the subcommittee, I would like to thank you for the opportunity to address the subcommittee regarding current Federal law and DEA regulations which allow for the importation of controlled substances under the personal medical use exemption.

I would also like to extend my personal condolences to the Rode family. Mr. Chairman, on behalf of Administrator Marshall, I would like to thank the subcommittee for its interest and support in assisting the DEA in carrying out our mission of enforcing the Nation's drug laws.

The U.S. is party to two international treaties which control the international trade in licit narcotic and psychotropic substances: The United Nations Single Convention on Narcotics of 1961; and the United Nations Convention on Psychotropic Substances of 1971.

The DEA is designated as the U.S. competent authority for ensuring the U.S. meets its obligations under these treaties. A critical obligation is our regulation and control of the import and export of licit narcotic and psychotropic substances.

The U.S. law pertaining to licit controlled substances is contained in the Controlled Substances Act of 1970. Enforcement of the CSA is the responsibility of the DEA. The FDA also plays a critical role in regard to controlled substances.

As the Federal authority for regulating all controlled and non-controlled prescription drugs from a health and safety perspective, the FDA's authority is contained in the Food, Drug, and Cosmetic Act.

Thus, controlled substances are subject to regulation by both the FDA and DEA. Together, the FDCA and the CSA provide a framework to protect the health and safety of the American public, and collaboratively, the DEA and FDA strive for consistent application of Federal laws.

Additionally, the United States Customs Service is responsible for enforcing the import and export provisions of the CSA at U.S. land borders. The CSA contains a personal medical use exemption to allow international travelers, both U.S. citizens and others, to

leave and enter the U.S. with controlled substances for their personal legitimate medical use.

This exemption is consistent with the 1971 Convention on Psychotropic Substances. The treaty clearly seeks to provide a means to allow international travelers to carry personal use quantities of controlled substance medications while visiting foreign countries.

The CSA exemption does the same. However, neither the treaty nor the U.S. statutes permit controlled substances to be imported under the medical use provision via overnight courier, unaccompanied baggage, parcel service, U.S. or international mail.

Nor does the exemption permit one person to enter the U.S. with controlled substances intended for the personal use of another person. The Controlled Substances Trafficking Prohibition Act was introduced in the U.S. House of Representatives on April 1, 1998, to amend the medical use exemption.

It was signed into law by the President on November 10, 1998. The Act addressed the fact that large quantities of controlled substances were being brought into the U.S. from Mexico by individuals misusing the exemption in order to divert pharmaceutical controlled substances into illicit channels.

The bill amended the Controlled Substances Act to prohibit any U.S. resident from entering the U.S. with more than 50 dosage units of a controlled substance through a land border crossing with Mexico or Canada unless they could demonstrate they possessed a valid prescription for the substance, and it was issued by a properly licensed U.S. physician.

This does not mean that any U.S. resident may enter the U.S. with up to 50 dosage units of a controlled substance, no questions asked. Rather, the resident must satisfy all the requirements set forth in 21 CFR 1301.26.

This includes the requirement that the importation is authorized or permitted under other Federal and State law. For example, if there is evidence that the drugs are not for legitimate personal medical use, and the same person makes repeated attempts over a short period of time to import new packages of controlled substances for claimed personal medical use, or the person has a variety of different controlled substances under circumstances that are indicative of diversion, the importation does not comply with either 9569a)(1), or the DEA regulations, and therefore must be disallowed.

Since the passage of the Act, the DEA has received information from the U.S. Customs Service that indicates that individuals are circumventing provisions of the personal medical use exemption.

We are currently considering ways of addressing this problem, such as amending our regulation to provide the clarity and guidance that the Customs Service needs to develop a clear, concise, and enforceable policy for its inspectors at the Nation's borders.

Before concluding, I would like to thank my colleagues at the FDA and U.S. Customs Service, and ONDCP for their cooperation in addressing this very important issue. Finally, Mr. Chairman, I think you and the members of the subcommittee for the opportunity to comment on this topic. I look forward to addressing any questions that you may have.

[The prepared statement of Laura M. Nagel follows:]

PREPARED STATEMENT OF LAURA M. NAGEL, DEPUTY ASSISTANT ADMINISTRATOR,
OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMINISTRATION

Chairman Greenwood, Ranking Member Deutsch, and other members of the Subcommittee, I would like to thank you for the opportunity to address this Subcommittee regarding current federal law and DEA regulations which allow for the importation of controlled substances under the personal medical use exemption. Mr. Chairman, on behalf of Administrator Marshall, I would like to thank the Subcommittee for its interest and support in assisting the Drug Enforcement Administration (DEA) to carry out our mission of enforcing the Nation's drug laws.

The United States is a party to two international treaties which control the international trade in licit narcotic and psychotropic substances: the United Nations Single Convention on Narcotics (1961) and the United Nations Convention on Psychotropic Substances (1971). The DEA is designated as the U.S. competent authority for ensuring that the United States meets its obligations under these treaties. A critical obligation is DEA's regulation and control of the import and export of licit narcotic and psychotropic substances.

The U.S. law pertaining to licit controlled substances is contained in the Controlled Substances Act of 1970 (CSA). Enforcement of the CSA is the responsibility of the DEA. The Food and Drug Administration (FDA) also plays a critical role with regard to controlled substances. As the federal authority for regulating all controlled and non-controlled prescription drugs from a health and safety perspective, the FDA's authority is contained in the Food, Drug and Cosmetic Act (FDCA). Thus, controlled substances are subject to regulation by both the FDA and the DEA. Together, the FDCA and the CSA provide a framework to protect the health and safety of the American public, and collaboratively, DEA and FDA strive for consistent application of federal laws. Additionally, the United States Customs Service is responsible for enforcing the import and export provisions of the CSA at U.S. land borders.

The CSA contains a personal medical use exemption to allow international travelers, both U.S. citizens and others, to enter and leave the U.S. with controlled substances for their legitimate personal medical use. Specifically, Section 950(a) of the CSA, entitled "Exemption Authority, Individual Possessing Controlled Substance," states that the "Attorney General may by regulation exempt from sections 952(a) and (b), 953, 954 and 955 of this title any individual who has a controlled substance (except substances in Schedule I) in his possession for his personal medical use, or for administration to an animal accompanying him, if he lawfully obtained such substance and he makes a declaration (or gives such other notification) as the Attorney General may by regulation require."

This exemption is consistent with the 1971 Convention on Psychotropic Substances. Article 4 (a) of the Convention states, with respect to psychotropic substances other than those in Schedule I, parties may permit: "The carrying by international travellers of small quantities of preparations for personal use; each Party shall be entitled, however, to satisfy itself that these preparations have been lawfully obtained[.]" The official commentary to the treaty explains the purpose of this provision: "[This provision] applies only to small quantities needed for personal use, i.e. to such quantities as the traveller may require during his journey or voyage and until he is able to provide himself with the medicine in question in the country of destination... In view of the express provision that each Party (i.e. the countries of transit and destination) is entitled to satisfy itself that the preparations have been lawfully obtained, it would be useful to require the traveller to carry a medical prescription or in cases in which the prescription is withheld by the pharmacist, a duplicate or satisfactory copy of the prescription showing that the preparations have been lawfully acquired."

Clearly, the treaty seeks to provide a means to allow international travelers to carry personal use quantities of controlled substance medications while visiting foreign countries. The CSA exemption does the same; however, neither the treaty nor U.S. statutes permit controlled substances to be imported under the personal medical use provision via overnight courier, unaccompanied baggage, parcel service, U.S. or international mail. Nor does the exemption permit one person to enter or depart the U.S. with controlled substances intended for the personal medical use of another person.

As set forth in the DEA regulation on this issue, 21 CFR Section 1301.26, anyone who seeks to import a controlled substance for personal medical use must satisfy all of the following requirements:

- (a) The controlled substance is in the original container in which it was dispensed to the individual; and
- (b) The individual makes a declaration to an appropriate official of the U.S. Customs Service stating:

- 1) The controlled substance is possessed for his/her personal use, or for an animal accompanying him/her;
- 2) The trade or chemical name and the symbol designating the schedule of the controlled substance if it appears on the container label, or if such does not appear on the label, the name and address of the pharmacy or practitioner who dispensed the substance and the prescription number, if any; and
- (c) The importation of the controlled substance for personal medical use is authorized or permitted under other Federal laws and state law.

The "Controlled Substances Trafficking Prohibition Act" ("the Act") (Pub. L. 105-357), was introduced in the U.S. House of Representatives on April 1, 1998, to amend the Personal Medical Use Exemption. It was signed into law by the President on November 10, 1998. The Act addressed the fact that large quantities of controlled substances were being brought into the U.S. from Mexico by individuals misusing the exemption in order to divert pharmaceutical controlled substances into illicit channels. The bill amended the CSA to prohibit any U.S. resident from entering the U.S. with more than 50 dosage units of a controlled substance through a land border crossing with Mexico or Canada unless they demonstrate that they possess a valid prescription for the substance, issued by a properly licensed U.S. physician. This does *not* mean that any U.S. resident may enter the United States with up to 50 dosage units of a particular controlled substance "no questions asked." Rather, the resident must satisfy all the requirements set forth in 21 CFR 1301.26. States may impose additional requirements as well.

For example, if there is evidence that the drugs are not for legitimate personal medical use (e.g., the same person has made repeated attempts over a short time period to import new packages of controlled substances for claimed personal medical use; or the person has a variety of different controlled substances under circumstances that are indicative of diversion), the importation does not comply either with §956(a)(1) nor the DEA regulations and must, therefore, be disallowed.

Furthermore, the requirement specified in 21 CFR 1301.26(c)—that the importation for personal medical use is authorized or permitted under other Federal laws and state law—must be satisfied regardless whether the person importing is a U.S. resident with no more than 50 dosage units of a controlled substance. For example, if a person were seeking to import a particular controlled substance for personal medical use, and the Food and Drug Administration advised the United States Customs Service that importation of the drug should be disallowed under the Food, Drug, and Cosmetic Act, the importation would not comply with 21 CFR 1301.26(c) and would have to be denied.

In the same way, if a person sought to import a controlled substance for purported personal medical use when entering the United States in a border state that prohibits either the importation or possession of the controlled substance, such importation must be disallowed under 21 CFR 1301.26(c).

Since the passage of the Act, DEA has received information from the United States Customs Service that indicates that individuals are circumventing provisions of the Personal Medical Use Exemption by making repeated trips across the border to obtain controlled substances. We are currently considering ways of addressing this problem, such as amending DEA's regulations to provide the clarity and guidance that the Customs Service needs to develop a clear, concise and enforceable policy for its inspectors at the Nation's land borders.

Before concluding, I would like to thank my colleagues at the Food and Drug Administration, the United States Customs Service, and the Office of National Drug Control Policy for their cooperation in addressing this very important issue. Finally, Mr. Chairman, I thank you and the members of this Subcommittee for the opportunity to comment on this topic. I look forward to addressing any questions that you may have at the appropriate time.

Mr. GREENWOOD. The Chair thanks the gentlelady for her testimony, and recognizes Mrs. Elizabeth Durant from the U.S. Customs Service for hers.

TESTIMONY OF ELIZABETH G. DURANT

Ms. DURANT. Mr. Chairman, and members of the committee, thank you for this opportunity to testify. I am Elizabeth Durant, Executive Director of Trade Programs at the U.S. Customs.

Today, I would like to discuss with you the U.S. Customs' efforts to address the rising trend of personal and bulk importations of pharmaceutical products into the United States. I would also like

to extend our sympathy on behalf of the U.S. Customs to the Rode family.

The Customs Service enforces over 400 regulations for more than 40 other Federal agencies at U.S. borders. These include the laws that prohibit the importation of illegal or unapproved pharmaceuticals that fall under the jurisdiction of both the FDA and DEA.

The Customs Services is concerned with three particular aspects of the importation of pharmaceuticals; those that are purchased through the Internet and shipped through our international mail facilities; those carried into the United States by individuals transiting our land borders; and imports of bulk shipments of pharmaceuticals.

The growth of the Internet has spawned a wave of pharmaceutical purchases on-line. These purchases are most commonly sent through the U.S. mail. We have Customs Inspectors stationed at 14 international mail branches at postal facilities across the United States to contend with these shipments.

Detecting prohibited pharmaceuticals among the tens of millions of parcels passing through our mail facilities each year presents a massive challenge. Our limited resources require a risk management approach with which we utilize advance intelligence, records of past seizures, and other factors to locate packages that present the most significant threat.

Customs laboratories also play a critical part in our investigations. Their expertise is world-renowned. We maintain fully equipped labs at seven locations around the country. In addition, we have three mobile labs to deploy at any point along our borders.

We are confident in the forensic capability of our labs to find discrepancies in shipments of bulk and finished pharmaceuticals. But where we do require assistance, specifically from the Food and Drug Administration, is in the establishment of effective national standards for the interdiction of pharmaceuticals subject to FDA laws.

The development of such standards is critical to customs. To that end, we have been working closely with FDA to develop the needed guidelines. We began by forming a joint task force to examine pharmaceutical purchases shipped by U.S. mail.

The task force set up a pilot in Los Angeles at the Carson mail facility. During that time the FDA detailed four full-time employees, who observed first-hand the daunting volume of packages screened by Customs every day.

Over a period of 24 work days, the FDA detained a total of 721 parcels, or just over 93 percent of this amount were denied entry, and only 44 were released. It is important to note that without the presence of FDA inspectors, U.S. Customs would have had to detain 3,000 packages per week, or about 16,000 packages over an equal time span under the existing guidelines provided to your personnel.

In light of these results, we understand that the FDA is revising its current policy to reflect a more practical and workable approach. Customs is working with the FDA to devise additional means to improve screening for these products.

However, we are awaiting the FDA's final policy before we decide whether or not to move ahead with these initiatives. Travelers who

attempt to import pharmaceuticals upon their return to the U.S. are also a source of concern.

Again, we are seeking guidance from FDA and DEA on this front. Recently, Customs proposed a plan that more sharply defines the current broad discretion given to Customs Inspectors to decide whether or not an importation is for a legitimate personal medical use. That plan is currently under review by both agencies.

While the Customs Service is currently focusing a great deal of effort on the interdiction of finished pharmaceuticals, we also recognize the threat posed by the importation of bulk pharmaceuticals.

In meetings with the Pharmaceutical Security Institute and other members of the pharmaceutical security community, the problem of counterfeit bulk pharmaceuticals continues to be a priority.

PSI asserts the opinion that foreign trade zones that produce finished pharmaceuticals habitually import cheap counterfeit bulk pharmaceuticals to support their production. In response, Customs initiated a multi-faceted counterfeit pharmaceutical interdiction program called Operation Safeguard.

Operation Safeguard was carried out between September and October of 2000 at the International Mail Branches at Dulles Airport and Oakland, California. The operation was intended to give Customs a snapshot of the types of pharmaceutical products entering the United States.

That snapshot revealed that a vast percentage, perhaps as much as 90 percent of the pharmaceuticals that enter the U.S. via the mail do so in a manner that violates FDA and/or DEA requirements.

Counterfeit pharmaceuticals enter in both wholesale and retail quantities. Additional problems include expired materials, products that have not been approved by the FDA, products made in facilities not under proper regulation, and products not having the proper usage instructions.

To offer an example, our seizures included a 3,000 tab shipment of a counterfeit drug with an expiration date of 1980.

Under the second stage of Operation Safeguard, scheduled to begin shortly, Customs will focus on bulk pharmaceuticals processed in various facilities around the country, including foreign trade zones. This will help us to determine the level of counterfeiting taking place.

In addition, our Office of Investigations is continuing to work with the FDA and DEA to combat the sale of prohibited pharmaceuticals via the Internet. Customs' CyberSmuggling Center is playing a leading role in these cases. Our efforts to date have included a successful investigation with authorities in Thailand that closed down seven on-line pharmaceutical sites operating in that country.

Just last March, Thai authorities, again using information developed by Customs, executed three search warrants at the headquarters of an illegal Internet pharmacy marketing steroids and Viagra.

From an overall perspective, a spiraling volume of goods at our borders has put immense pressure on our ability to enforce the Na-

tion's laws while facilitating international trade. We have taken many steps to address the anticipated challenges.

I want to thank you and the members of the committee for considering the Customs Service in your review of the importation of personal and bulk pharmaceuticals. This is an issue that speaks directly to our mission.

We will continue to make every effort possible to work with Congress and our fellow inspection agencies to address the health and safety concerns of the American people. Mr. Chairman, we have a short video. If you have time, we would like to show you so that you can see.

Mr. GREENWOOD. Without objection, we would be delighted to see the video.

[Video shown.]

Ms. DURANT. This is a video of operations at our mail facility at Dulles International Airport. You can see that the mail comes to us on conveyer belts delivered from the Postal Service. We x-ray all packages of foreign mail. From the x-rays and other factors, based on the experience of our inspectors, sort from this vast number to determine those that present the greatest risk for evasion.

The Dulles facility receives approximately 70,000 packages a week. I know, because I was just in Memphis that our Fed Ex hub receives 70,000 packages a night. So it is quite a daunting task for us to refine our sorting so that we have the best chance of capturing those that are at most risk to the American public.

You can see the kinds of drugs that come in through the mail. They are not even in bottles many times, just loose in paper. We have counterfeit drugs. We have grey market drugs. We have prohibited drugs, and we have unapproved drugs, the whole gamut of illegal substances through our mail facility at Dulles. This is a situation that is pretty much replicated around the country.

While many of the illegal substances are smuggled and are hidden on purpose, some are just in packages, in boxes. I guess they figure they will take their chances that we won't catch them. This is a daily occurrence at Dulles. Thank you.

Mr. Chairman, I have a few examples to show you of the kinds of things that we find that we know could not possibly be for personal use. This first parcel is multiple types of prescription drugs in a single package. This particular package was imported from Thailand. We believe it's for black market distribution in the United States. We believe that these kinds of shipments then go to garage type pharmacies that may be operating domestically in the United States, as well as the ones overseas.

These are grey market drugs which are available in the United States. We don't know what the strength of them is. There is no guarantee that the user has the correct warning implications, all the issues this committee brought up earlier today about the supervision of taking prescription drugs that's needed.

This is a scheduled substance. This is actually fen-phen, which has been prohibited in the United States.

This substance is gammahydroxybutyrate, which is used in conjunction with the date rape drug. It is used in club scenes known as liquid X. It is linked to date rape because of the confusion and unconsciousness that it causes.

This is your seizure, Mr. Chairman. This is the amylnitrate labeled as Jungle Juice, that you saw when you were out at our Dulles facility. So you can see it is an amazing array of the different types of things that we're finding every day.

Thank you, sir. I will be happy to take questions later.

[The prepared statement of Elizabeth G. Durant follows:]

PREPARED STATEMENT OF ELIZABETH G. DURANT, EXECUTIVE DIRECTOR OF TRADE PROGRAMS AT THE U.S. CUSTOMS SERVICE

Mr. Chairman, members of the Committee, thank you for this opportunity to testify. I am Elizabeth Durant, Executive Director of Trade Programs at the U.S. Customs Service. Today I would like to discuss with you U.S. Customs' efforts to address the rising trend of personal and bulk importations of pharmaceutical products into the United States.

The Customs Service enforces over 400 regulations for more than 40 other federal agencies at U.S. borders. These include the laws that prohibit the importation of illegal or unapproved pharmaceuticals that fall under the jurisdiction of both the FDA and DEA.

The Customs Service is concerned with three particular aspects of the importation of pharmaceuticals: those that are purchased through the Internet and shipped through our international mail facilities; those carried into the United States by individuals transiting our land borders, and imports of bulk shipments of pharmaceuticals.

The growth of the Internet has spawned a wave of pharmaceutical purchases online. These purchases are most commonly sent through the U.S. mail. We have Customs Inspectors stationed at fourteen international mail branches at postal facilities across the United States to contend with these shipments. These facilities are located at New York's John F. Kennedy Airport; Newark, New Jersey; Dulles Airport in Virginia; Chicago, Detroit, Buffalo, Miami, Dallas, Charlotte, Honolulu, Carson Airport in Los Angeles, Seattle, and Oakland/San Francisco.

Detecting prohibited pharmaceuticals amongst the tens of millions of parcels passing through our mail facilities each year presents a massive challenge. Our limited resources require a risk management approach, with which we utilize advance intelligence, records of past seizures, and other factors to locate packages that present the most significant threat.

Customs laboratories also play a critical part in our investigations. Their expertise in analyzing everything from textiles, to foreign oil, to food products to determine point of origin and composition is world-renowned. We maintain fully equipped labs at the following locations: New York; Chicago; Savannah; New Orleans; Los Angeles; San Francisco and San Juan. In addition, we have three mobile labs to deploy at any point along our borders.

We're confident in the forensic capability of our labs to find discrepancies in shipments of bulk and finished pharmaceuticals. But where we do require assistance, specifically from the Food and Drug Administration, is in the establishment of effective national standards for the interdiction of pharmaceuticals subject to FDA laws.

The development of such standards is critical to Customs. To that end, we have been working closely with FDA to develop the needed guidelines. We began by forming a joint task force to examine pharmaceutical purchases shipped by U.S. mail. The task force set up a pilot program in Los Angeles at the Carson mail facility. The pilot ran for thirty days, from January 15th through February 15th of this year. During that time, FDA detailed four full-time employees who observed first-hand the daunting volume of packages screened by Customs every day.

Over a period of twenty-four work-days, the FDA detained a total of 721 parcels. 677 parcels, or just over 93 percent of this amount, were denied entry and 44, or six percent, were released for delivery by the Postal Service. It is important to note that without the presence of FDA inspectors, U.S. Customs would have had to detain some 3,000 packages per week, or about 15,000 packages over an equal time span, under the existing guidelines provided to our personnel.

In light of these results, we understand that the FDA is revising its current policy to reflect a more practical and workable approach. Customs is working with the FDA to devise additional means to improve screening for these products, such as implementation of a pre-approval process and the installation of digital cameras in mail facilities to supplement staffing shortfalls. However, we are awaiting the FDA's final policy before we decide whether or not to move ahead with these initiatives.

Travelers who attempt to import pharmaceuticals upon their return to the U.S. are also a source of concern. Again, we are seeking the guidance of the FDA and

DEA on this front. Recently, Customs proposed a plan that more sharply defines the current broad discretion given to Customs inspectors to decide whether or not an importation is for a "legitimate personal medical use". That plan is currently under review by both agencies.

While the Customs Service is currently focusing a great deal of effort on the interdiction of finished pharmaceuticals, we also recognize the threat posed by the importation of bulk pharmaceuticals. In meetings with the Pharmaceutical Security Institute (PSI) and other members of the pharmaceutical security community, the problem of counterfeit bulk pharmaceuticals continues to be a priority. PSI asserts the opinion that foreign trade zones that produce finished pharmaceuticals habitually import cheap counterfeit bulk pharmaceuticals to support their production.

In response, Customs initiated a multi-faceted counterfeit pharmaceutical interdiction program called "Operation Safeguard". Operation Safeguard was carried out between September and October of 2000 at the International Mail Branches at Dulles Airport and Oakland, California. The operation was intended to give Customs a snapshot of the types of pharmaceutical products entering the United States. That snapshot revealed that a vast percentage—perhaps as much as eighty to ninety percent—of the pharmaceuticals that enter the U.S. via the mail do so in a manner that violates present FDA and/or DEA requirements. Counterfeit pharmaceuticals enter in both wholesale and retail quantities. Additional problems include expired materials, products that have not been approved by the FDA for usage, products made in facilities not under proper regulation and products not having the proper usage instructions. To offer an example, our seizures included a three thousand-tab shipment of a counterfeit drug with an expiration date of 1980 on it.

Additionally, it was found that many parcels contained different types of pharmaceuticals that, if taken simultaneously, could cause dangerous interactions. These products could easily be purchased by individuals not under the direct supervision of a physician. Thus, we cannot assume that they would be used properly.

It is important to note that after three weeks of Operation Safeguard, the quantity of illegal and defective pharmaceutical shipments slowed significantly.

Under the second stage of Operation Safeguard, scheduled to begin shortly, Customs will focus on bulk pharmaceuticals processed in various facilities around the country, including Foreign Trade Zones outside the United States. This will help us to determine the level of counterfeiting taking place.

In addition, our Office of Investigations is continuing to work with the FDA and DEA to combat the sale of prohibited pharmaceuticals via the Internet. Customs' CyberSmuggling Center is playing a leading role in these cases. Our efforts to date have included a successful investigation with authorities in Thailand that closed down seven, on-line pharmacy sites operating in that country. As a result, we saw a marked decrease in subsequent pharmaceutical seizures from Thailand. Just last March, Thai authorities, again using information developed by Customs, executed three search warrants at the headquarters of an illegal Internet pharmacy marketing steroids and Viagra.

From an overall perspective, a spiraling volume of goods at our borders has put immense pressure on our ability to enforce the nation's laws while facilitating international trade. We have taken many steps to address anticipated challenges, including refinement of our targeting approach and development of a resource allocation model to project future staffing needs across the country. But we still face a daunting workload.

I want to thank you and the members of the Committee for considering the Customs Service in your review of the importation of personal and bulk pharmaceuticals. This is an issue that speaks directly to our mission. We will continue to make every effort possible to work with the Congress and our fellow inspection agencies to address the health and safety concerns of the American people.

Mr. GREENWOOD. We thank you very much for your testimony.

The Chair recognizes Dr. Alan Leshner, Director of the—I apologize. Next we will hear from Mr. William Hubbard of the Food and Drug Administration.

TESTIMONY OF WILLIAM K. HUBBARD

Mr. HUBBARD. Thank you, Mr. Chairman. I am joined by John Taylor and Jeffrey Shuren from FDA in case we need further expertise. I, too, have cluttered up your table, and I apologize for that. Of course I have written testimony for the record.

Mr. Chairman, the committee has been examining a number of issues dealing with drug safety, counterfeiting, foreign inspections, controlled substances, and personal importation. I would like to focus today on the personal importation issue, if I may.

When I testified here last May on Internet sales, I think that we and the committee agreed that the State and Federal authorities had the tools and the will to perhaps get some of the domestic sites under control with various existing laws, perhaps supplemented by new laws that might be necessary. But I think we recognized at the time that the bigger problem was foreign sites. We were very concerned about that. I think we were right, because these things that Ms. Durant and others are showing you and the things I have in front of me are evidence of that.

We took some of the same sorts of samples and asked physicians at FDA to tell us about them, what they are. Of course, they do come in the same way that Ms. Durant stated—this is one with four drugs in it, four packages. Inside is a little bag of pills. We don't know what that is. So it's a wide variety. We have injectibles from Spain. We have a seasonal allergy drug that's approved here in a form, but this one is not. We have an over-the-counter drug. We have an anti-psychotic drug. We have drugs for heart conditions. We have oxycontin. We have an interesting one here. This is labeled as a seasonal allergy drug, but if you look more closely, inside is a controlled substance. I'm not sure the folks at the ports will be able to very easily make that distinction.

So we see a wide range of these sorts of products. They really do pose risk. As you saw when you came to Dulles, they come in packages with clothing and personal effects, all kinds of things. They are very small packages that really overwhelm our ability to do much with them.

So we have been examining this issue, Mr. Chairman. We have been surveying the drugs that come in. We have been consulting with our sister agencies, and we have been carefully considering what to do about this. The inescapable conclusion for us is that these drugs are virtually all unapproved in the United States. They are provided without proper manufacturing controls. They often lack instructions for safe use, and they may be counterfeit, or worse. These factors, combined with the rapid increase in the Internet that's caused the explosion of these things, leads us to believe that they pose a risk to our citizens that must be reduced.

So, accordingly, we have recommended to Health and Human Services Secretary Thompson that he approve our recommendation to request that the Customs Service deny entry of all of these drugs, and to return them to their sender. We would create one exception for patients with serious diseases, such as cancer, who need an unapproved drug from a foreign country to save their life, at least to give them hope of saving their life. We would need to set up some sort of a compassionate use process to allow those drugs in. But that would be the only exception.

I will say that if the administration agrees with us on this, we are going to need to come back to the Congress, because now the process requires us to give the recipients of these products notice. If you take our data from the California example and extrapolate it to an annual rate, it's perhaps 2 million of these a year at cur-

rent rates, and perhaps growing. We can't go through the process that we must now go to, which is to mail a letter to the recipient, receive a response back, and go through that 2 million times. We need to be able to make a blanket assessment that these things are not safe for American consumers and should be turned back. I believe the Customs Service agrees with that. So if Secretary Thompson and the administration agree, that will be the approach we intend to take.

[The prepared statement of William K. Hubbard follows:]

PREPARED STATEMENT OF WILLIAM K. HUBBARD, SENIOR ASSOCIATE COMMISSIONER
FOR POLICY, PLANNING AND LEGISLATION, FOOD AND DRUG ADMINISTRATION

INTRODUCTION

Mr. Chairman and Members of the Committee, I am William K. Hubbard, Senior Associate Commissioner for Policy, Planning and Legislation, Food and Drug Administration (FDA or the Agency). I appreciate the opportunity to discuss our mutual concerns related to the importation of drugs into the United States (U.S.). This topic encompasses a range of issues, including the importation by individuals of prescription drugs at land borders or through the mail; the introduction into the U.S. of controlled substances from foreign sources under the guise of personal importation; the potential introduction of counterfeit bulk drugs into the U.S. drug supply; and the purchase of drugs from foreign sources over the Internet. We appreciate the leadership this Committee has taken in keeping these issues at the forefront. Let me begin by discussing one of our greatest challenges in this area.

PERSONAL IMPORTATION OF DRUGS THROUGH THE MAIL

The amount of prescription drugs for personal use imported through the mail has increased in recent years. According to testimony by the U.S. Customs Service (Customs) before the Government Reform Committee in May of last year, seizures of parcels containing scheduled or controlled substances at international mail facilities increased by 450 percent in FY 1999, primarily due to drug sales over the Internet. We estimate that approximately two million parcels containing FDA-regulated products for personal use enter the U.S. each year through international mail facilities that Customs could set aside for FDA review for possible violations of the Federal Food, Drug, and Cosmetic (FD&C) Act. This estimate is based on an extrapolation of data obtained during a pilot project conducted at the international mail facility in Carson, California (see below).

Under the FD&C Act, unapproved, misbranded, and adulterated drugs are prohibited from importation into the U.S., including foreign versions of U.S.-approved medications, as is reimportation of approved drugs made in the U.S. In general, all drugs imported by individuals fall into one of these prohibited categories.

From a public health standpoint, importing prescription drugs for personal use is a potentially dangerous practice. FDA and the public do not have any assurance that unapproved products are effective or safe, or have been produced under U.S. good manufacturing practices. U.S.-made drugs that are reimported may not have been stored under proper conditions, or may not be the real product, because the U.S. does not regulate foreign distributors or pharmacies. Therefore, unapproved drugs and reimported approved medications may be contaminated, subpotent, superpotent, or counterfeit. In addition, some foreign web sites offer to prescribe medicines without a physical examination, bypassing the traditional doctor-patient relationship. As a result, patients may receive inappropriate medications because of misdiagnoses, or fail to receive appropriate medications or other medical care, or take a product that could be harmful, or fatal, if taken in combination with other medicines they might be taking.

Personal Importation Policy

Under FDA's personal importation policy, as described in guidance to the Agency's field personnel, FDA inspectors may exercise enforcement discretion to permit the importation of certain unapproved prescription medication for personal use.

First adopted in 1954, the policy has been modified several times over the succeeding years. It was last modified in 1988, in response to concerns that certain potentially effective treatments for AIDS patients were not available in the U.S., but were available in other countries. The Agency expanded the guidance for humanitarian purposes to allow individuals suffering from serious medical conditions to ac-

quire medical treatments legally available in foreign countries but not approved in the U.S.

The current policy permits the exercise of enforcement discretion to allow entry of an unapproved prescription drug if:

- the product is for personal use (a 90-day supply or less, and not for resale);
- the intended use is for a serious condition for which effective treatment may not be available domestically (and, therefore, the policy does not permit inspectors to allow foreign versions of U.S.-approved drugs into the U.S.);
- there is no known commercialization or promotion to U.S. residents by those involved in the distribution of the product;
- the product is considered not to represent an unreasonable risk; and
- the individual seeking to import the product affirms in writing that it is for the patient's own use and provides the name and address of the U.S. licensed doctor responsible for his or her treatment with the product or provides evidence that the product is for the continuation of a treatment begun in a foreign country.

FDA has not officially permitted the importation of foreign versions of U.S.-approved medications, even if sold under the same name, because these products are unapproved, and the Agency has no assurance that these products are safe or effective, while safe and effective versions are already available in the U.S.

FDA believes that the need for its personal importation policy is far less now than it was when the current version of the policy was developed in 1988. Now, due to faster review times and various regulatory mechanisms through which patients can obtain unapproved treatments for humanitarian purposes, the need to import therapies not available in the U.S. has diminished. According to a Tufts University study presented in September 2000, 80 percent of new molecular entities approved in the U.S. in 1996 through 1998 received that approval within a year of its first introduction on the world market, almost double the rate during the years 1991 through 1995.

Implementation of the Personal Importation Policy

At mail facilities, Customs officials identify parcels that may be violative of the FD&C Act. FDA inspectors then determine if these products should or should not be permitted to enter the country. If detained, FDA must issue a notice to the addressee describing the potential Federal violation and provide the individual with an opportunity to respond. If the addressee does not respond or provides an inadequate response, FDA will give the parcel back to Customs to have it returned to the exporter. Due to the requirements for notice and the opportunity to respond, the process for detaining and further processing mail parcels consumes large amounts of FDA resources. In addition, much storage space would be needed to hold the large number of detained parcels pending replies from the addressees.

FDA's personal importation policy, as written, is difficult to implement. This is due, at least in part, to the difficulty faced by FDA inspectors, or even health care practitioners, in identifying a medicine by its appearance, and labeling may falsely identify a product. From a practical standpoint, FDA inspectors cannot examine drug products contained in a mailed parcel and accurately determine the identity of such drugs or the degree of risk posed to the individual who will receive these drugs.

FDA detains and refuses few mail imports for personal use. As a consequence, the tens of thousands of parcels that FDA does not review are eventually released by Customs and sent on to their addressees, even though the products contained in these parcels may appear to violate the FD&C Act and may pose a health risk to consumers. We do not believe this is an acceptable public health outcome and are working to develop a solution.

HHS Plan to Address Mail Imports for Personal Use

Due to the inability of FDA to cope with the volume of medications imported for personal use through the mail, and because of the public health risks associated with these products (as discussed below), FDA has been working to develop a more effective personal importation policy. In addition, we recognize that Customs is dependent on guidance from FDA, and one of our goals is to provide clear and simple standards for assessing parcels containing drug products. We are discussing options for revisions to the Agency's personal importation policy with Secretary Thompson.

CARSON MAIL FACILITY PILOT

Earlier this year, FDA and Customs conducted a survey of imported drug products entering the U.S. through the Carson City, California mail facility (the Carson pilot). The Carson pilot was proposed by Customs as a means to examine incoming mail shipments of pharmaceutical products over a specified time frame in order to

identify both the volume and the types of drug products entering the U.S. We also hoped to better assess the efforts required to cover drug importations at a mail facility, and to gain a better understanding of the public health implications these importations may have for U.S. consumers.

The Carson pilot ran for a five-week period, with FDA inspectors present for 40 hours per week. At the onset, Customs took a "baseline" sample in the first week by setting aside all international packages that were suspect, or that they would have set aside for FDA review had FDA been able to process them. The number of packages set aside was approximately 3,300. Multiplying that number by five weeks provides an estimated total of 16,500 international packages (650 packages per day) that Customs could have set aside for FDA review during the Carson pilot, if the ability to process them was not a factor. After the first week, however, Customs actually set aside the number of packages they believed FDA would be able to examine. In general, during each week of the Carson pilot, more packages were set aside than FDA was able to handle.

FDA was actually able to examine 1,908 packages during the five-week pilot, an average of approximately 381 packages per week. Neither FDA nor Customs kept a count of the packages that were set aside but not examined. Unexamined packages were sent on to the addressees.

Of the 1,908 packages examined by FDA, 721 parcels were detained and the addressees notified that the products appeared to be unapproved for use in the U.S., misbranded and/or a drug requiring a doctor's prescription. The parcels were shipped from a total of 19 countries, and overall, there was no obvious evidence of the products being imported for further commercial distribution. On average, the Agency was detaining at a rate of 144 packages per week, or about 38 percent of those examined.

Clearly, the Carson pilot demonstrated that the rate of packages coming into the U.S. exceeds FDA's capacity to manage, thus, Customs is left with little choice but to forward the majority of packages to addressees. As we stated, we do not believe this is an acceptable public health outcome, and we are working to develop a solution.

Analysis of the Carson Pilot Drug Parcels

In order to define better the nature of the risk to public health from the types of products coming into the U.S. through personal importation, FDA's Center for Drug Evaluation and Research (CDER) reviewed listings of the products detained during the Carson pilot. CDER's review demonstrates that there are serious public health risks associated with many of the 721 drug shipments (composed of 197 different drugs) intercepted at Carson. In general, there are two types of risks that consumers of these drugs would face. The first type of risk is that associated with taking drugs of unknown origin or quality. Second are the very significant risks associated with taking many of these drugs without first obtaining a physician's prescription and without the continued oversight of the physician.

Risks Associated with Drugs of Unknown Origin or Quality

In general, FDA has no information to establish where these drugs were actually manufactured and whether necessary current Good Manufacturing Practice requirements were followed. There is also no assurance that the drugs were packaged and stored under appropriate conditions to avoid degradation or contamination.

Approximately eight percent of the shipments contained drugs that could not be identified because they contained no labeling; some of these contain only foreign language labeling. Most of these drug shipments were contained in plastic bags; one shipment contained drugs taped between magazine pages.

Several drugs do not appear to correspond with any U.S.-approved drugs and the risks are therefore difficult to assess. One drug was evaluated for FDA approval but was denied approval. This drug is associated with cardiac abnormalities and its efficacy could not be successfully demonstrated. Another drug approved abroad but not in the U.S. is associated with medically serious gastro-intestinal complications. Several shipments contained three drugs that were once approved by FDA but have been withdrawn from the market based on serious safety concerns, including:

- fatal arrhythmia and dangerous drug interactions;
- loss of white blood cells (agranulocytosis) associated with fatal infections; and
- hemorrhagic stroke.

Risks Associated with the Absence of Physician Oversight

The vast majority of the shipments were identified as containing prescription drugs, which by definition, have serious toxicities and risks associated with them such that they are "not safe for use except under the supervision of a practitioner

licensed by law to administer such drug" (Title 21, *United States Code*, section 353(b)). Although some foreign Internet sites might offer an online questionnaire, we believe that very few, if any, require a prescription from a practitioner licensed in the U.S. before dispensing such drugs to U.S. residents. Moreover, after detention notices were issued to the intended recipients of the 721 drug shipments, fewer than four percent presented evidence of prescriptions to document their relationship with a physician in association with the drugs purchased from abroad. The lack of adequate English language labeling accompanying many of these shipments exacerbates the risks associated with the absence of physician oversight.

During the Carson pilot, as in normal practice, Customs generally separated out controlled substances for processing by the Drug Enforcement Administration (DEA) before the remaining shipments were provided for FDA review. However, in FDA's review, six controlled substances were identified, including lorazepam, codeine sulfate, loperamide, chlorthalidone, chloral hydrate, and diphenoxylate. These drugs have the potential to cause addiction or be abused. Life-threatening overdoses are possible. A physician's prescription and oversight are essential for managing these risks.

There are numerous drugs identified on the Carson list that are intended to treat conditions that consumers need physicians to properly diagnose. As a result, consumers who bypass physician diagnosis and prescribing may be exposing themselves to risks and toxicities that cannot be justified by offsetting benefits to those patients.

- For example, almost ten percent of the shipments were for antibiotics, despite the fact that consumers are generally not able to diagnose whether their symptoms are caused by bacterial infections. The overuse of antibiotics continues to be a serious public health concern because it is linked to the growth of antibiotic-resistant bacteria.
- Several drugs listed are potent steroids, which are generally prescribed for conditions that are not self-diagnosable. In addition, potential adverse events associated with these drugs, including diabetes, hypertension, and serious infection require prompt attention and careful monitoring.

There are many drugs on the list for which it is essential that the proper dose be delivered into the bloodstream at the proper rate. Some of these drugs have a narrow range in which they can safely achieve their therapeutic effect. At least seven such drugs were identified on the Carson list. Without FDA oversight, there is the risk that these drugs may not have been manufactured with the necessary quality controls to ensure a consistently safe and effective product.

- One seizure medication on the Carson list, for which there were three shipments, could be very dangerous if not manufactured to these rigorous standards. Any change in potency could render the drug ineffective or highly toxic.
- Another seizure drug on the list for which physician monitoring is also essential has a narrow therapeutic range and FDA labeling provides a black-box warning for hepatotoxicity, teratogenicity, and pancreatitis.

More than 30 drugs on the list have serious contraindications and/or drug interactions for which physician oversight is essential. For instance, almost 20 percent of the shipments were for various estrogen products for which there are multiple serious contraindications that a physician needs to consider before making prescribing decisions and in monitoring the patient.

It is impossible to make a scientifically definitive statement on the public health impact of the drug shipments encountered during the Carson pilot without extensive chemical testing and analysis of the incoming pharmaceuticals, which would be prohibitively expensive. Based on the observations noted above, however, FDA believes that these drugs pose substantial risks to the public health, and we further believe that significant changes to the policies governing personal importations through the mail are warranted.

BORDER SURVEYS

Over the last year, FDA has initiated three other surveys to gather data on drug products imported by individuals into the U.S. Although these border surveys involve land traffic rather than mail importation, the results of these surveys show some similarities to the findings from the Carson mail pilot, as well as some significant differences.

Southwest Border Survey (August 2000)

A survey of prescription drugs being brought by pedestrians into the U.S. at eight ports of entry along the 2,000 mile border with Mexico was conducted by FDA's Southwest Import District (SWID) with the assistance of other agencies including

Customs, the DEA, the U.S. Department of Agriculture, and others. The survey looked at activity during four hours on a Saturday (August 12, 2000) at eight border ports in California, Arizona, and Texas. The purpose of the survey was to interview individuals walking across the border into the U.S. from Mexico who had purchased prescription drugs in Mexico to determine 1) what specific types of products are being imported, and 2) who is importing these products.

The data collected from over 600 interviews indicated that the most common importer of prescription drugs during the survey was an older male Caucasian with a prescription from the U.S., bringing back primarily antibiotics or pain relievers for his own use. Prescriptions were held by 63 percent of the persons interviewed (59 percent U.S. prescriptions and 41 percent Mexican). The most common drugs and their indications that were purchased in Mexico during the survey were as follows: Amoxicillin (antibiotic), Glucophage (diabetes),

Premarin (estrogen), Dolo Neurobion (vitamin supplement), Vioxx (inflammation), Retin-A (acne), Tafil (anxiety), Celebrex (arthritis), Penicillin (antibiotic), Viagra (impotence), Carisoprodol (analgesic).

Canadian Border Survey

On January 6, 2001, in cooperation with Customs, FDA conducted a survey to obtain a snapshot of prescription drug products being brought into the U.S. from Canada via passenger vehicles. During the eight-hour survey at three ports of entry in New York, Michigan and Washington, a total of 10,374 passenger vehicles and 58 buses crossed into the U.S. Of these, 33 passenger vehicles (35 individuals) were referred by Customs to be interviewed. These individuals brought in a total of 47 containers of drug products from Canada.

The types of products included pain medicines—primarily “222” (a combination of acetaminophen, caffeine, and codeine) or similar products. The indicated reason for import was that the products were available over the counter in Canada and cost less than in the U.S. The next largest group of products was herbal products, with the reason for importation being that the products were not available in the U.S. Other products included Tobradex (antibiotic/steroid ophthalmic for individuals having laser eye surgery); Claritin and Allegra (allergies) purchased over-the-counter (OTC) in Canada; Sibelium capsules (calcium channel blocker); and a variety of OTC products sold in Canada and not available in the U.S.

Southwest Border Survey (April 2001)

On April 11, 2001, FDA, Customs, and other agencies conducted a survey of prescription drugs being brought into the U.S. at seven ports of entry along the U.S./Mexican border. This survey coincided with both Easter vacations from many colleges and the end of the “snowbird” season, when tourists from Northern states visiting along the Southern border return home.

During the four hour “blitz” a total of 586 persons brought in a total of 1,120 drugs. Approximately 56 percent had a prescription for the medicines (61 percent were U.S. prescriptions, 39 percent were Mexican). The most common drugs purchased in Mexico were: Amoxicillin (antibiotic), Premarin (estrogen), Claritine (allergy), Terramycin (antibiotic), Ampicillin (antibiotic), Ibuprofen (analgesic), Penicillin (antibiotic), Vioxx (inflammation), Tafil (anxiety), Dolo Neurobion (vitamin supplement), Glucophage (diabetes), Celebrex (arthritis), Naproxen (analgesic), Retin-A (acne), Ventolin (pulmonary disease), and Valium (controlled substance/nervous system depressant).

CONTROLLED SUBSTANCES

Although we do not know, nor is it possible to clearly determine, the amount of controlled substances brought into the U.S. purportedly for personal use, it is likely that such medicines are frequently imported for resale and pose a public health risk. The Agency has been working with both Customs and DEA to streamline and clarify Federal import policies specifically related to the importation of controlled substances.

Counterfeit Bulk Drugs

As we stated in testimony before this Committee last year, FDA believes that the authenticity and quality of drugs dispensed in the U.S. remains high. We do take very seriously, however, any allegation regarding the possible counterfeiting or adulteration of imported bulk drugs, also referred to as active pharmaceutical ingredients (APIs). The Agency agrees that more should be done to help ensure that imported bulk drugs (APIs) and finished drug products meet the requirements of the FD&C Act. We are actively pursuing a number of initiatives to better detect and prevent the importation of counterfeit or adulterated APIs.

Let me provide the Committee with a brief update on the five initiatives that we announced at the hearings last year.

1. **In February 2000, additional funds were allocated to the Forensic Chemistry Center (FCC) by the Office of Regulatory Affairs (ORA) for sampling, analytical work and assessments of APIs gathered through targeted inspections of importers.**

During FY 2000, the FCC conducted 20 targeted inspections, including nine at importers of foreign APIs, ten at domestic finished dosage manufacturers and one at a domestic animal drug manufacturer. The FCC collected more than 1,000 samples of 130 APIs and related documents and records during the inspections. Samples of two drug substances have been analyzed.

The information and results of analysis obtained during the investigations indicate a need for follow-up at two foreign API manufacturers. Provisions are being made to have ORA laboratories in New York and San Juan assist in the analytical evaluation, and some training has already been provided.

2. **Make the FCC API database available electronically to all field inspectors by January 2001.**

Direct electronic access to the FCC's API database was made available to all District offices beginning in January 2001. Enhancements to the system's capabilities and training for the user community are ongoing and we expect to complete these efforts by the end of the current FY. Information continues to be added to the API database, which currently contains 566 label images and other packaging information for foreign APIs. This database is one important tool that FDA can use to more quickly identify whether or not a product is authentic or counterfeit.

3. **Expand the Philadelphia pilot nationwide by the end of 2000.**

A pilot program was begun in the Philadelphia District office in 1997, to provide import inspectors with access to information on the approval status of drug applications, as contained in the Establishment Evaluation System (EES) database maintained by CDER. Access to this data allows inspectors to obtain relevant approval information in about three to four minutes on any API entry, which increases the probability of confirming that the API being offered for import is from a proper foreign source manufacturer and is intended for use by an appropriate end-user.

The program has now been expanded to all of our districts. In December 2000, ORA provided training to field import personnel nationwide on the use of the EES database. Since then, District Offices have been actively using EES to insure that imported APIs are, when required, shipped from a firm identified as an approved source in the finished dosage manufacturer's new drug application (NDA). FDA's inspectors report that access to EES information has been very useful in helping to assure that the declared source and destinations of imported APIs are appropriate.

The Operational and Administrative System for Import Support (OASIS) records indicate that 12 API entries have been refused admission since January 1, 2001, based upon the appearance that the API was misbranded because it was not from an approved source for use in the manufacture of a finished dosage drug requiring an NDA. OASIS records indicate that under the guidance relating to the use of EES for evaluation of API entries, FDA has detained 499 distinct entry lines of imported APIs among 437 API entries since January 1, 2001. However, all but the 12 refused shipments were resolved when Districts received evidence that the API was intended for a use other than an application finished dosage manufacturing process or was manufactured by an approved source. Consequently, the vast majority of these entries were released into commerce after FDA review.

4. **Put all importers and customs house brokers on notice that they are required to provide the name of the foreign manufacturer upon entry into the U.S., and that the entry of their products into the U.S. will be contingent upon it.**

Last year, the Agency placed the import and customs broker industries on notice regarding the existing requirement to provide FDA with accurate data regarding the identity and location of the manufacturer of imported drugs. Although these requirements were previously communicated to importers and brokers on a number of occasions, we were not satisfied with the level of compliance with this requirement. On July 20, 2000, the Agency posted an updated version of this requirement on the Internet with links to and from FDA's import operations pages. On July 28, 2000, a Customs Automated Broker Interface (ABI) system administrative message regarding this requirement was issued to all brokers.

Compliance with this requirement is routinely assessed as the Agency carries out filer evaluations and is one of the factors considered in providing continued elec-

tronic filing privileges on OASIS. Customs has informed FDA that these types of reporting failures may be the basis for Customs civil actions. Since January 2001, FDA has initiated four separate cases with Customs requesting broker penalties against brokers who have failed to provide adequate or accurate data to FDA when they filed entries. In three of these cases, Customs has approved the requests, while a fourth case is pending. Since June 1, 2000, 12 filers have been removed from paperless status and are required to submit paper entry documents due to their failure to electronically transmit accurate data for a variety of FDA products.

5. Require domestic manufacturers to provide information to FDA when they discover that the bulk materials they receive are substandard, ineffective, or appear not to be from the approved source.

FDA is concluding the process of drafting a proposed regulation to require such reports, which would apply to both domestic and foreign manufacturers. We appreciated the Committee's suggestion to initiate this requirement.

Let me now provide you with a brief update on some other initiatives.

API Quality Sampling and Analytical Surveys

ORA and CDER are planning to perform a sampling survey in FY 2002 targeting imported APIs for quality and, where indicated, authenticity evaluation. This survey, which is now being designed by CDER and ORA, will broadly evaluate the quality of foreign manufactured APIs, and specifically target APIs that are potentially substandard or counterfeit.

Information Technology (IT) Assessment and Enhancement

We know that one of the issues of great concern to the Committee is the Agency's lack of a well-integrated IT system for the regulation of drug imports. FDA currently relies on several independently developed databases of critical information that need to be integrated.

Last July, FDA engaged the services of a private contractor to assess the Agency's IT needs for import operations and to recommend changes to provide field staff with ready access to the information necessary for making informed admissibility decisions. ORA has already implemented several IT enhancements. First, electronic access to Agency data sources are being provided to all FDA resident posts, either by wide area network (WAN) or by satellite technology. Second, ORA is initiating the establishment of an enterprise portal system, which will provide a common user interface to all of FDA's information databases. The statement of work containing the technical requirements for this project has been drafted and the Agency hopes to award a contract for system design by July 2001. Through these initiatives, FDA plans to provide more information to its field inspectors and investigators on a much more consistent basis through a single information access point.

Joint FDA-Customs Pilot Targeting Broker Misdeclarations

FDA is currently piloting a joint operation with Customs in one U.S. port to specifically target FDA filers that have demonstrated a pattern of inaccurately declaring information material to FDA's admissibility decisions (whether in drug entries or other regulated commodities). Available remedies against repeat offenders include a possible FDA request that Customs demand physical redelivery of the shipments entered using inaccurate information, and an initiation of broker penalties, which may be substantial. FDA has seen recent success in initiating civil broker penalties when filers fail to provide correct data for FDA's evaluation upon entry. Much of this success is a direct result of cross training of FDA's import operations field and headquarters personnel in Customs law and regulations and civil remedies that are currently available to FDA when an importer or broker fails to adhere to declaration or FDA examination requirements.

INTERNET DRUG SALES

Based on surveys conducted in early 2000 by Office of Criminal Investigations (OCI) and subsequently by the General Accounting Office (GAO), it appears that there are roughly 300 to 400 Internet sites selling prescription drugs, with approximately half located domestically and half located outside the U.S. FDA has long taken the position that consumers are exposed to a number of risks when they purchase drugs from Internet sites or other mail order outlets that dispense foreign drugs. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong product, a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use. FDA cannot provide consumers with any assurance that these products were manufactured under current good manufacturing practice standards. Taking an unsafe or inappropriate medication

puts consumers at risk for dangerous drug interactions and other serious health consequences.

Internet sites that provide prescription drugs by having consumers fill out a questionnaire rather than seeing a doctor pose serious health risks. A questionnaire generally does not provide sufficient information for a healthcare professional to determine if that drug is appropriate or safe to use, if another treatment is more appropriate, or if the consumer has an underlying medical condition where using that drug may be harmful. FDA has undertaken widespread public relations efforts to warn consumers about the dangers of buying drugs online, and we have provided extensive information on these dangers on FDA's own Internet site. FDA's Buying Medical Products Online web page is one of the most frequently requested pages on FDA's website. It consistently ranks among the top twenty requested pages, averaging almost 13,000 hits per month.

Currently, FDA has 90 sites under active review for possible regulatory or civil action. Warning letters have been sent to 48 domestic online sellers. Additionally, FDA has sent 121 "cyber letters" to operators of Internet sites offering to sell online prescription drugs or unapproved drugs. These sites may be engaged in illegal activity such as offering to sell prescription drugs to U.S. citizens without valid (or in some cases without any) prescriptions. Cyber letters are sent over the Internet to the suspect websites to warn the operators that they may be engaged in illegal activities, and inform them of the laws that govern prescription drug sales in the U.S. While cyber letters may not be the most effective enforcement tool, they certainly have a deterrent effect and FDA has seen positive results from using them. FDA has received positive responses from twenty percent of the cyber letter recipients and we are continuing to monitor these sites.

FDA also sends copies of its cyber letters to the home governments of targeted websites, when the locations can be identified. Follow-up depends on the ability and willingness of the foreign regulatory bodies to investigate and take actions against website operators who are illegally shipping drugs to other countries.

In cooperation with the Department of Justice (DOJ), five preliminary injunctions have been imposed on the sale of illegal products, including one product marketed as a weight-loss aid containing a potent thyroid hormone which could cause heart attacks or strokes, and an unapproved cancer therapy. FDA and DOJ also are pursuing an injunction against the sale of another unapproved cancer therapy over the Internet. Additionally, 15 product seizures, 11 product recalls, and the voluntary destruction of 18 violative products have been achieved, generally pertaining to unapproved new drug products including gamma hydroxybutyric acid, gamma butyrolactone, Triax, 1,4 butanediol, and laetrile. Thirty-six foreign shippers have been placed on Detention Without Physical Examination and added to Import Alert 66-57 for targeting sales of unapproved new drug products to the U.S.

During FY 2001, FDA's OCI initiated approximately 40 Internet-related investigations and will continue to conduct investigations involving suspected criminal activity related to Internet drug sales as well as other Internet-facilitated criminal violations of the FD&C Act. Of the 133 currently open Internet-related investigations, 64 are Internet pharmacy cases, where the focus is on the possible dispensing of prescription drugs without a prescription.

In recent years, OCI has initiated 285 Internet investigations and each of these investigations have involved a variable number of actual websites—typically ranging from one to 25 or more. OCI has effected 88 Internet-related arrests, 70 of these in drug-related investigations. Of the 70 drug-related arrests, 11 have involved Internet pharmacy cases. These arrests have resulted, thus far, in 48 Internet-related convictions, 42 of these in drug-related investigations. Of the 42 drug-related convictions, five have involved cases involving the sale of prescription drugs without a valid prescription.

In addition, OCI has an ongoing initiative at the Dulles International Airport Mail Facility that had its genesis in their first Internet case, which began in 1994. The case, which involved a site selling steroids over the Internet, resulted in a successful prosecution and shutdown of the website. The partnership resulting from this case has continued, and in the past 18 months, OCI has been involved with local law enforcement in the Washington metropolitan area in 98 drug seizures. The seizures represent dozens of types of drugs coming in from 13 different countries. Of the 98 seizures, 87 of the drug seizures were ordered over the Internet and mailed to U.S. citizens; six were mailed to the U.S. by family or friends living abroad; four were ordered via a 1-800 telephone number from Canada and mailed to the U.S.; and one was transported via an airline passenger in two suitcases from Romania. The efforts of OCI, Customs, and local law enforcement have yielded the execution of eight search and seizure warrants and led to the arrest and prosecution of nine people.

CONCLUSION

Mr. Chairman, FDA remains concerned about any possibility that counterfeit or otherwise unsafe drugs may find their way into the American drug supply. We will remain vigilant as we refine and improve the programs and procedures that we use to ensure the availability of safe medications for consumers.

We appreciate the continued interest of the Committee in these important issues, and look forward to continuing to work with you. Thank you again for the opportunity to participate in today's hearing. I will be happy to answer any questions.

Mr. GREENWOOD. The Chair thanks the gentleman for his testimony, and calls upon Dr. Alan Leshner, Director of National Institute on Drug Abuse.

TESTIMONY OF ALAN I. LESHNER

Mr. LESHNER. Good morning, Mr. Chairman, members of the committee. Thank you for the opportunity to join this distinguished panel and comment on some of the scientific aspects of prescription drug abuse. Like my colleagues, I would like to extend our sympathy to the Rode family for their terrible loss.

Let me start by emphasizing that from a public health point of view, many substances can be two things at once. On the one hand, medications like morphine and methylphenidate are extremely effective when used properly as prescribed. They can save lives, and they certainly improve the quality of life for millions of Americans.

However, when these same substances are misused, they can be highly addictive, dangerous, and even fatal drugs. Right now, we are seeing the prescription drug misuse or abuse as posing a major public health threat.

A variety of indicators that I have gone through in my written statement in much greater detail suggests that prescription drug misuse is increasing. For example, according to SAMHSA's National Household Survey on Drug Abuse, more than 9 million Americans reported that they used prescription drugs for non-medical reasons at least once in 1999. One-quarter of them, over 2 million people, acknowledged that they had begun their prescription drug abuse in that 1 year.

Now prescription drug abuse, of course, is not a new problem. It has been around for a long time. What is particularly alarming right now is the significant increase in misuse and the increase in young, first-time users of these drugs. The most dramatic increases are found in 12- to 17-year-olds, and 18- to 25-year-olds. Depending on the specific drug, between 60 and 90 percent of the abusers are in these age groups. These adolescents and young adults of course are at tremendous risk of wasting the potential of their lives.

Now we don't know for certain why people are abusing increasing amounts of prescription drugs, but we believe that the ready availability and all of the glorification of these drugs are contributing to the problem. It has long been known that changes in the perception of risk or changes in the perception of harm always drive drug use rates. For that reason, we and a variety of partners in April launched a major prescription drug abuse education and research initiative to try to get ahead of the increasing rates in prescription drug misuse.

We also believe that people are developing their addictions through different pathways. There is one group who are intentionally abusing these drugs, just as one might abuse so-called

street drugs, like heroin or crack cocaine. But there also appears to be another group who may initially begin to use these medications appropriately as prescribed, but over time they slowly begin to deviate from their prescription regimen for some reason. Then they may find that they have become addicted, without ever planning or attempting to abuse the drug in the first place.

It is important to mention here, however, that it is extremely rare for people to become addicted when medications are taken as prescribed. As just one example, the combined data from three clinical studies showed that in patients with no prior history of drug abuse, using opiates for the treatment of pain was associated with only seven cases of addiction out of a total sample of 25,000 people. This tells us that pain can be addressed safely using opiate medications without over-concern about addiction, but only so long as patients are well educated about their use.

The stimulant methylphenidate, known commonly as Ritalin, is another example of a drug that's extremely beneficial when used as prescribed, but can be very dangerous when abused.

I will stop here. I would be pleased to answer any questions that you may have. I do want to thank you for bringing added attention to this very important issue, and for asking that biomedical science be a part of this hearing. Thank you very much.

[The prepared statement of Alan I. Leshner follows:]

PREPARED STATEMENT OF ALAN I. LESHNER, DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Chairman, and Members of the Subcommittee, I am pleased to be here to present what science has taught us about psychoactive prescription drugs and their potential for abuse. This discussion is particularly timely given that the National Institute on Drug Abuse (NIDA) has recently launched a major initiative on prescription drug abuse and misuse. NIDA's renewed efforts to encourage more research into this area and to educate the public about the consequences of abusing prescription drugs is a preemptive strike on our part to curtail what our surveillance systems suggest is a growing problem in this country.

At the outset, I would like to emphasize that many substances can be two things at once. They can be very effective medications when used properly; and highly addictive, dangerous, substances when misused. When used for legitimate medical purposes, controlled substances such as morphine and diazepam (Valium®), improve the quality of life for millions of Americans with debilitating diseases and conditions. It is only when these medications are used improperly that they begin to pose a serious public health threat. It is the increasing use of these medications for purposes other than how they were intended that is of growing concern to us.

Several indicators suggest that prescription drug misuse and abuse are increasing in the U.S. population. We know that in 1999 more than 9 million Americans aged 12-and-older reported that they used prescription drugs at least once in the past year for non-medical reasons. One quarter or more of those 9 million people misused prescription drugs for the first time in the year prior to the survey. And 4 million reported that they used prescribed medications for non-medical reasons in the past month. These data come from the National Household Survey on Drug Abuse, supported by the Substance Abuse Mental Health Services Administration.

NIDA's own Community Epidemiology Work Group, a network of epidemiologists and researchers from 21 major U.S. metropolitan areas who monitor and report on community-level trends in drug use and abuse, are also seeing increases in abused prescription drugs. The latest CEWG report, for example, reports that the opioid hydrocodone (e.g. Lorcet, Lortab, Vicodin) appears to be one of the mostly widely abused prescribed medications. The number of emergency room mentions of hydrocodone has grown by 139 percent, or from 6,115 mentions in 1993 to 14,639 in 1999. Other prescribed drugs that are emerging on the scene and are causing increases in emergency room visits, according to CEWG, are oxycodone and clonazepam.

Prescription drug abuse is not a new problem. The significant increase in the numbers of people misusing these prescription drugs is what is new. From 1990 to 1998, for example, the number of individuals initiating misuse or abuse of pain relievers increased by 181%, new initiates to stimulants have increased by 165%; tranquilizers by 132%; and initiates into sedative use have increased by 90%. The most dramatic increases are found in 12-17 year-olds and 18 to 25 year-olds. Females in this younger age bracket appear to be particularly vulnerable to prescription drug abuse.

Determining one's vulnerability to addiction is an important part of NIDA's research portfolio. The fact that we do not fully understand what makes some individuals more vulnerable to addiction than others makes our concern about prescription drugs even more compelling. There are major differences among individuals in sensitivity to various drugs of abuse. Using advanced technologies, we recently found that differences in brain chemistry may be one of the factors that predisposes people to respond differently to abusable drugs. Other determinants of drug use preferences and patterns include genetic and environmental factors, a possible underlying medical illness, as well as factors such as the availability of drugs.

What is significant about the brain chemistry finding that I just mentioned is that all abusable drugs—from alcohol and nicotine, to cocaine, methamphetamine, and morphine—share some common mechanisms of action. They all activate the neurotransmitter dopamine, which is part of the reward pathway or pleasure center for the body. It is this pleasurable effect that is likely the reason that 26.2 million Americans used an abusable drug in the past year in 1999.

Although dopamine is a common factor among all drugs of abuse, each class of drug acts at different sites in the brain to produce its intended effect. For example opiates, such as morphine, codeine, and oxycodone, work predominantly at the mu opioid receptors found in the brain and spinal cord, to block the transmission of pain messages to the brain.

Another commonly abused class of drugs is the Central Nervous System (CNS) depressants. CNS depressants modulate actions of gamma-aminobutyric acid (GABA) to slow down normal brain function. This resulting calming effect is what makes CNS depressants so useful in the treatment of anxiety and sleep disorders. Barbiturates such as mephobarbital and pentobarbital; and benzodiazepines such as diazepam and alprazolam, are two categories of CNS depressant medications that are commonly prescribed for anxiety and sleep disorders.

The final class of commonly abused prescription drugs that I will briefly mention today is stimulants. As the name suggests, stimulants are a class of drug that enhance brain activity. They cause an increase in alertness, attention, and energy by displacing two of the brain's key neurotransmitters, norepinephrine and dopamine, which in turn increases blood pressure, heart rate, respiration, and blood glucose. Stimulants such as dextroamphetamine, methylphenidate, and sibutramine are generally prescribed for narcolepsy, attention-deficit hyperactivity disorder, obesity, as well as depression, and asthma.

When taken properly all of these prescription drugs that I have just mentioned can be extremely helpful in relieving a wide variety of medical problems. It is when they are used non-medically, that prescription drugs can be dangerous, addicting and even deadly.

Research has not yet completely revealed all the reasons why people would abuse a prescribed medication. Some may just intentionally abuse these drugs to receive the pleasurable effects, in the same way that people abuse and become addicted to heroin or crack cocaine. Others seem to begin to use them appropriately as prescribed, but then over time they slowly begin to deviate from the prescription regimen and may become addicted without ever intentionally setting out to abuse the drug in the first place. It is important to note that physical dependence does not equal addiction. Physical dependence can be relatively easily managed, whereas addiction—the compulsion to use drugs—is a chronic reoccurring illness that requires long-term treatment.

As I mentioned earlier, the same substance can be both a very effective medicine and a dangerous addictive drug. Morphine, is the perfect example. Morphine is a powerfully addictive drug. However, when it is used to treat pain it is an extremely beneficial medicine. The medical use of prescribed opiates effectively relieves both chronic and acute pain, and allows millions of individuals to function normally. Addiction under these circumstances is very rare. In fact, the combined data from three clinical studies found that in patients with no prior history of abuse, opiates used for the treatment of pain was associated with only 7 cases of addiction in a sample of about 25,000 people.

Another example of how beneficial medications can be when used as prescribed can be seen with the stimulant methylphenidate, known commonly as Ritalin®.

Data accumulated over 30 years shows that methylphenidate is a safe medication when appropriately used for the treatment of attention-deficit hyperactivity disorder (ADHD). ADHD affects about 3 to 5 percent of the general population and is now one of the most visible childhood mental disorders. A number of studies indicate that ADHD youth that are appropriately treated with stimulant medications have a reduction in the risk of later substance abuse.

In conclusion, I would like to thank you for allowing me to be here to have science be a part of your discussion on this topic. NIDA is increasing its research efforts into this area and will be pleased to keep you abreast of any new findings that emerge that may help guide your policy decisions.

Mr. GREENWOOD. Thank you for your testimony.

The Chair recognizes for his testimony, Sergeant Gibbs.

TESTIMONY OF LANDON S. GIBBS

Mr. GIBBS. Good morning. My name is Landon Gibbs. I am an Assistant Special Agent in charge of the Drug Enforcement Division within the Virginia State Police. I supervise a unit that concentrates solely on pharmaceutical drug diversion and abuse.

I want to speak to you about three things basically this morning. The first is a drug that's causing tremendous problems within Virginia. It's called Oxycontin. I want to talk to you about what that drug is, how it is abused, and more importantly, I want to talk to you about how it is impacting the communities in Virginia by the rapid onset of abuse. Then I would like to address some of the personal importation that we have made cases on in Virginia.

Oxycontin is a very effective pain drug.

Mr. GREENWOOD. Pull your microphone just a tad closer, please, Sergeant. Thank you.

Mr. GIBBS. Oxycontin is manufactured to relieve from severe to moderate pain, terminal pain, a very effective good drug when used as prescribed. The problem comes in when it is used otherwise.

The drug abuser in Virginia will take the drug and crush it, and either chew it and swallow it, inject it, or snort it. When the drug is crushed, it bypasses its time release formulation, which gives the abuser the full impact of pure Oxycodone in a rush. It creates a high similar to heroin.

When it is used in this fashion it becomes extremely addictive, and the person gets hooked on it very, very quickly. They develop a mindset that all they want is more and more of the drug. They will do whatever it takes to obtain that drug.

This is how it is affecting the communities in certain parts of Virginia. The crime rates, particularly property crime, have skyrocketed in some of the rural areas where these people are burglarizing homes to find anything they can to sell, to buy the drug. There are increased armed robberies of pharmacies, where they actually go in at gun point, bypass the cash register, and go straight to the drug stock or ask the pharmacy techs to give me the Oxys. That's all they are after.

The drug is extremely profitable if they can steal it, even if they are not an addict, because it sells for about a dollar a milligram on the streets. This drug is now available in 10, 20, 40, and 80 milligram strengths. So if I can steal a bottle of 100 40-milligram pills, I have got \$4,000 that I can sell very, very quickly.

The abuse problem increases to the point that women will become prostitutes to obtain money to buy the drug. They will steal from their families. They don't work any more. It has created a tre-

mendous financial impact on those communities. Unfortunately, the experiences that Mr. and Mrs. Rode told you about today is not uncommon. Virginia has experienced about 50 overdose deaths related to this one drug within the last year.

It is not just one drug that causes the problem. As they have mentioned today, there is significant number of drugs, but the Schedule IIs are the ones that appear to be causing the deaths of the people that abuse it.

Going back to the personal importation of the drug, we have experienced that in Virginia. For a number of years, we heard rumors about people bringing Oxycontin and other drugs in from Mexico. With the system of allowing 50 dosage units per person, again, we'll go back to the 40 or the 80-milligram pill. As you can see, the financial incentive for a person to go across, obtaining a drug such as Oxycontin in Mexico and bring it back.

We recently were working cases in cooperation with the DEA and made several arrests of individuals who would go into Mexico, and each person would bring 5,000 dosage units of Oxycontin back. The pharmacists at the little border towns would actually help them conceal the drugs on their body because they knew that the Customs Service would x-ray packages or bags, purses, and things like that. So they would tape or hide the medication on their bodies themselves.

After they were arrested, this group of six submitted three separate trips of obtaining 5,000 dosage units each to bring back into Virginia to sell. They were arrested when they were selling it back in the State.

In April of this year, I went to the border crossing at Tijuana personally. Quite frankly, I was overwhelmed at what I saw. It is hard to imagine the volume of vehicles and individuals coming into the United States from Mexico. On this particular day, I made a mistake and drove across the border. I missed the exit. You are not supposed to do that with a rental car, but I did. There was so much traffic coming back, I waited in line for about an hour to get through the border crossing, and was simply waved through, as were hundreds of cars. I parked the car on the U.S. side and walked back into Mexico and spoke with Customs officers working there. There were only three that day, trying to handle the bus and foot traffic across. I spoke to him about the problems that we are having with people importing the drugs. He said if you look at the volume of traffic that we have, you will understand why we are so overwhelmed, that there is very little enforcement effort that can be done.

They were doing as much as they could such as x-raying purses and suitcases and things like that. But for the individuals that were not carrying this baggage, they just simply came across.

I watched a child of about 14 on roller blades make two trips. He would go across the border into Mexico, roller blade back across and meet some people in a parking lot on the U.S. side, and then go back. I was quite certain of what that young man was doing.

The importation is a serious problem. Most of the problems that we are having with pharmaceutical drug abuse in Virginia is through over-prescribing by physicians. They are just prescribing, for example for Oxycontin, more than is truly medically needed.

That makes it available for sale on the street. Then once the person that is abusing it becomes addicted, then if the supply from the physician is cutoff, we have arrested several doctors for this, then they will go to Mexico or wherever they can to get it to bring it back in.

I have heard testimony today concerning having a valid prescription to obtain the stuff and import it. The validity of a prescription comes into play if you go on the Internet, fill out a form, and supposedly a physician will look at it in another State, perhaps, and issue a prescription.

Virginia passed a law last year that causes a prescription to be issued by a physician only when a true doctor-patient relationship exists. That code defines what that doctor-patient relationship is. It says there must be some type of an examination of the patient by the prescriber. That way, we are hoping to try to stop some of this Internet stuff from even getting a foothold in Virginia that way. So far, that has worked very, very well.

I will be glad to answer any questions that you have.

[The prepared statement of Landon S. Gibbs follows:]

PREPARED STATEMENT OF LANDON S. GIBBS, ASSISTANT SPECIAL AGENT IN CHARGE,
BUREAU OF CRIMINAL INVESTIGATION, DRUG ENFORCEMENT DIVISION, VIRGINIA
STATE POLICE

Good morning Mr. Chairman and members of the Committee. My name is Landon Gibbs. I am an Assistant Special Agent in Charge within the Drug Enforcement Division of the Virginia State Police. I thank you for the invitation to speak with you today concerning the impact of prescription drug abuse and the personal importation of one of the most abused drugs.

My testimony will focus on three areas:

A brief description of the drug Oxycontin, it's intended use and how it is abused
The impact on individuals and the community of Oxycontin abuse
Personal importation of prescription drugs

Oxycontin, its use and abuse

Oxycontin is a very effective analgesic, designed for moderate to severe pain relief, chronic pain control and terminal cancer pain relief. It is a time-released form of the narcotic analgesic Oxycodone. Oxycodone has a high abuse potential and is similar to Morphine in dependence liability.

Oxycontin is currently available in 10, 20, 40 and 80 mg tablets, as the manufacturer has ceased shipment of the 160-mg tablet. Oxycontin is pure Oxycodone, with no other active ingredients, as compared to other analgesics such as Percocet, Tylox and Percodan. The time release formulation allows patients 8 to 12 hours of pain relief from a single dose.

There are relatively few known incidents of addiction, or physical dependence, to Oxycontin when the drug is taken as prescribed by a physician. It becomes highly addictive when the time release formulation is bypassed by crushing the drug, then either inhaling the powder or mixing the powder with water and injecting the solution. This allows the abuser to receive the full effect of the pure Oxycodone almost immediately. This creates an effect similar to illicit opioid narcotics, such as heroin.

In Virginia, most of the Oxycontin sold on the street and abused comes from legitimate prescriptions written by physicians. It is quite obviously being over prescribed and prescribed to individuals who do not need it for pain relief.

Impact of abuse on individuals and communities

Individuals who abuse Oxycontin by inhaling or injecting the crushed tablets quickly become addicted. This creates a mindset in which the only goal of the individual is to obtain more of the drug. Interest in work, family and personal well being simply disappears. The individual often develops a drug-seeking behavior in which jobs, family, friends will all be sacrificed in an effort to obtain money to buy more Oxycontin. Thefts of money or items to sell from family members are all too common. Some result to prostitution or other criminal acts to fund their habit. Oxycontin has a street sale value of one dollar per milligram.

The community also suffers when Oxycontin, or other drugs, are abused by a significant number of the population. Virginia has had over 50 deaths related to Oxycontin abuse, through overdosing or combining the drug with other substances, such as alcohol or other prescription drugs. In addition to the emotional tragedy of these deaths, the financial impact on families, the community and welfare programs is quite significant. In southwest Virginia, local police are overwhelmed with the increase in property crime related to Oxycontin addicts. Armed robberies and burglaries of pharmacies are becoming a very real problem. Thefts from homes and business, writing bad checks, car jacking and other crimes are increasing as the drug addicted individuals seek anything they can sell for money to buy the drug.

In northern Virginia, a woman was arrested for illegal possession of Oxycontin and teaching her 15-year-old son how to crush and inhale the drug. In another case, an undercover buy of Oxycontin was made in a home where a 10-year-old was crushing the drug and preparing to inhale it, in the presence of his father. The drug is reportedly being widely abused by college students.

Personal importation of prescription drugs

Over the last two years, rumors have been heard concerning the street sale of Oxycontin that was obtained in Mexico. The price of the drug in Mexico is approximately ten cents per milligram. The street resale value in Virginia is one dollar per milligram. Under current federal guidelines, an individual is permitted to bring in up to 50 dosage units of a prescription drug. If that individual purchases 50 Oxycontin tablets of 80 mg each, he or she would pay approximately \$400 in Mexico. That same amount would be worth \$4,000 on the street in Virginia. I believe that what is taking place is that groups of people are making multiple border crossings in a short period of time to import this drug. The profit margin is very high. There is no risk of being detained at the border as no laws have been violated at this point.

The State Police, working with the Drug Enforcement Administration, have made several arrests of individuals selling Oxycontin that was obtained in Mexico. These individuals were traveling to Mexico and obtaining 5,000 dosage units each per trip. In statements made after their arrest, they said they purchased the Oxycontin for 10 cents per milligram and the Mexican pharmacists helped them conceal the drugs on their body. These individuals made at least three trips to Mexico and none were ever checked entering the United States. They remarked that as long as a person did not carry any bags or a large purse, the Customs officers would not do any serious checking or questioning.

In April of this year I visited the border crossing at Tijuana. The volume of vehicle and foot traffic entering the United States overwhelms the efforts of both the Immigration Service and the Customs Service. On this particular day there were only three Customs officers at this border crossing. One was assigned to deal with bus traffic and the other two dealt with foot traffic. I spoke with one Customs officer who stated that it is impossible for them to really check what is being imported. Hundreds of vehicles were streaming into the United States. On this day I did not see any being searched.

The importation of prescription drugs is a serious problem. If the importation is for a true medical need, then the issue of why such a significant price discrepancy between the United States and other countries is a matter of concern. And if the 50 dosage unit regulations stay in place, should the returning U. S. citizen be required to produce a copy of a U. S. issued prescription? If the importation is not based on medical necessity, then no amount should be permitted into this country.

Finally, all the importation regulations are, in reality, useless unless there is an effective system in place at the border to enforce them.

I thank you for the opportunity to speak with you today and will be glad to answer any questions.

Mr. GREENWOOD. Thank you for your testimony.

The Chair recognizes himself for 5 minutes for inquiry.

When we went out to Dulles Airport, we saw the overwhelming number of packages that were coming in. We saw how many of them contained pharmaceuticals, but we also saw that not only is Customs completely overwhelmed by the flow of illegal drugs into this country, but FDA completely overwhelmed given its current regime.

It seems to me we have two choices. We can throw up our hands and say it's an overwhelming volume coming in through the mail,

an overwhelming volume coming across the border in Mexico. We don't have the manpower. We don't have the resources to do anything about this. Then we can continue to bury kids in this country. We can bury kids as the Rodes did, 50 overdoses from one drug alone in Virginia. Or we can get serious about this and get down to a tolerance level that puts an end to this.

Now I am very pleased to hear the testimony from the Food and Drug Administration today that the recommendation has been made to the Secretary of Health and Human Services that in fact we don't throw our hands up. In fact, we get down to essentially zero tolerance. This is, to me, good news.

Now the question will be it is one thing to say that. It is one thing to say every single package that comes into the United States that has a drug in it, pharmaceutical product, legal in this country, not legal in this country, with a prescription, without a prescription it is going to be turned down except for a very minute percentage that might be for compassionate use. The question is, can that be implemented?

I want to address that question first to Customs, because you are first online. Then to the FDA. We are delighted that you come here to this hearing and tell us that this is going to be essentially a zero tolerance. The question is, can that be implemented? Are we likely to hear from the Health and Human Services Secretary that this will be the policy, go to work, shut this stream of dangerous drugs down, and feel that we have solved this problem? Or are we likely to hear that it is a nice idea, but it is impossible to enforce and we can't do it.

Ms. Durant?

Ms. DURANT. The Customs Service was also very pleased to hear this. We believe that this will, while we might miss one in the x-ray once and a while, our inspectors are very astute using the x-ray and other factors, packaging and some intelligence on occasion in the sort. For us administratively, this is a giant leap forward because we can then simply redeliver the mail to the Post Office and say return it. We do not today have the authority to refuse admission. So this would give us that ability. I think it would make a very big difference.

Mr. GREENWOOD. Do we need, either for Customs or for the FDA, do you need a change in the law to do this or just a change in the policy within the Food and Drug Administration?

Mr. HUBBARD. Well we have examined that, Mr. Chairman. We believe we might be able to do this by regulation. We actually have the authority now to stop this material. But as I said earlier, we have to go through these notice requirements that are so burdensome with the numbers and small staff we have, that it makes it, as a practical matter, impossible.

We think the better thing to do though would be to come to the Congress and get explicit authority to eliminate that notice, obviously just for these sorts of things, not for all shipments of things. Obviously commercial shipments of drugs and that sort of thing would continue under the existing regime.

Mr. GREENWOOD. Well, it seems to me that—and you and I have had this conversation informally—but it seems to me that what we have here is we have this firehose of drugs coming across the bor-

der and coming in through the mail. In part, we have it because the policies that have been in place, and the border policies that have been in place at the airports has been relatively permissive. It has been it's too much to handle kind of an approach.

It seems to me that if we take a zero, essentially zero tolerance, that what is going to happen is the people who are ordering these drugs are going to find that they never show up. Just as they found out through word of mouth, through the Internet, through Internet chatrooms that we have looked at some of the conversation that goes on in Internet chatrooms about how to get these drugs, just as they learned how to get them illicitly, they will begin to learn that the party is over, that they are not going to come in any more, and that they are going to waste their money.

When somebody uses a credit card or other means to pay for a drug that never arrives, one would assume that they would stop doing that, that their friends would stop doing that, that their associates would stop doing that. Eventually, these illicit facilities, both in Mexico, physical facilities and the cyber facilities, the websites that access drugs in other continents, would eventually go out of business for lack of demand.

So I am delighted to hear that this is going to be the recommendation. You can be assured that this Member of Congress, and I think the others on the panel, will support that recommendation to the Secretary, and that we will be more than happy to pass the legislation that is necessary in case there is any question with regard to your authority in this matter.

The Chair yields back the balance of his time, and recognizes Mr. Dingell for 5 minutes for inquiry.

Mr. DINGELL. Mr. Chairman, thank you for your courtesy.

Ms. Durant, two questions. A simple yes or no answer I think will suffice. In your Carson City project, in 4 or 5 weeks Custom inspectors could have stopped approximately 16,000 parcels containing pharmaceuticals or something that appeared to be a pharmaceutical. Is that correct?

Ms. DURANT. That is correct.

Mr. DINGELL. It is also true that FDA could process only a tiny fraction of these, approximately 30 a day? Is that right?

Ms. DURANT. That is also correct.

Mr. DINGELL. So they could only then have reviewed a minute portion of this?

Ms. DURANT. That is correct.

Mr. DINGELL. Now this to Food and Drug: That was because of lack of attention, lack of personnel, lack of money, or why?

Mr. HUBBARD. It is clearly lack of staff. We have 150 inspectors around the country to do import work, Mr. Chairman. We do not have the resources to look at these small packages.

Mr. DINGELL. Thank you.

Now, Ms. Durant, FDA could not handle this volume and Customs was forced to release about 14,000 parcels to customers without any formal FDA review. Is that right?

Ms. DURANT. Yes, sir.

Mr. DINGELL. That could have been controlled substances, Category 1 substances, which are absolutely forbidden either to manufacture, possess, or sell. Is that right?

Ms. DURANT. We have authority to make some seizures on our own authority.

Mr. DINGELL. But I am talking about the 14,000 that you released. That could have been anything?

Ms. DURANT. They were not all reviewed, then it could have been anything, yes, sir.

Mr. DINGELL. It could have been almost anything.

Now, Ms. Durant, FDA has written guidance to Customs that says as follows, "It is expected that a Customs Officer from the Customs Mail Division will examine a parcel and will set it aside if it appears to contain a drug, biological or device. Reality in the field: A small number of pharmaceuticals are referred to FDA by Customs and by the two IMBs. For the most part, if the parcel doesn't contain a scheduled substance, it is released back to the Postal Service for delivery." Is that right?

Ms. DURANT. Yes, sir.

Mr. DINGELL. That is a major contributor, if it not, to the situation that we confront?

Ms. DURANT. Yes.

Mr. DINGELL. Because Customs has to do the work, gets no examination or scrutiny by FDA, and almost anything can get by this rather curious kind of net. Is that right?

Ms. DURANT. It is an overwhelming challenge, yes.

Mr. DINGELL. Now, is it my understanding that currently we have 13 mail facilities across the country that process international mail? Is that correct?

Ms. DURANT. Yes, sir.

Mr. DINGELL. Now I would note that most major cities have such facilities in it, New York, Dallas, Miami, Washington, D.C.

Now, Ms. Durant, isn't it the case that similar to what we are experiencing in the Los Angeles facility, these other mail branch facilities are being overwhelmed?

Ms. DURANT. It is generally correct. The degree of being overwhelmed depends on the source country of the packages to those facilities, but that is generally correct.

Mr. DINGELL. And we must infer that this overwhelming is leading to a substantial risk of unsafe, counterfeit, or prohibited substances that should not be permitted in under the law. Is that right?

Ms. DURANT. Yes, sir.

Mr. DINGELL. Does Food and Drug deny this?

Mr. HUBBARD. Yes, Mr. Chairman. We see a huge diversity of every sort of drug you can imagine that's coming in these packages.

Mr. DINGELL. Thank you.

Now, Ms. Durant, isn't it the case that before the recent visit to the Dulles mail facility 2 weeks ago, in just 4 hours your inspectors found 160 parcels containing pharmaceuticals?

Ms. DURANT. Yes, sir.

Mr. DINGELL. Now isn't it true also that your agency is finding on a regular basis pharmaceutical products that are being shipped into this country that are expired, shipped in plastic bags with no labels or instructions as to their use, or pharmaceuticals that your agents can't even identify as FDA-approved products? Is that right?

Ms. DURANT. That is correct.

Mr. DINGELL. So this question to FDA. On these matters, you have no way of knowing whether these substances coming in meet the requirements that the United States has with regard to safety or efficacy of prescription pharmaceuticals. Indeed, you have no way of knowing whether they have been manufactured using good manufacturing practices?

Mr. HUBBARD. I would go even further, Mr. Dingell, and say they probably do not. Here is one particular package from Thailand. We spent a week with some of the best drug data in the world trying to find out what that is. There are three types of pills in here that we cannot determine what these pills are.

Mr. DINGELL. Was it addressed to a drug cartel member?

Mr. HUBBARD. No. It was addressed to a citizen in Northern Virginia, to the best of my knowledge.

Mr. DINGELL. Now, Ms. Durant, it is also the case your agency are seeing schedule I drugs, such as Ecstasy being blister wrapped and being sent into the United States through the mail. Is that not true?

Ms. DURANT. That is true.

Mr. DINGELL. Let me go over some of the findings you made regarding Operation Safeguard, and see if I understand them. There's one point that I want to address particularly. Not even a single parcel that you received in this met all of FDA's criteria for importation of prescription drugs. Is that so?

Ms. DURANT. That is so.

Mr. DINGELL. Not a single one?

Ms. DURANT. Not a single one.

Mr. DINGELL. Isn't it the case, Mr. Hubbard, that many of the thousands of the products being shipped into the United States are from unknown origins, that they pose considerable risks to consumers because they may be counterfeit, expired, super-potent, sub-potent, simply tainted, or mislabeled so as to constitute something other than what appears to be, possibly even including Schedule I substances?

Mr. HUBBARD. I think it is highly likely that is correct. Perhaps certainly correct.

Mr. DINGELL. Now, Ms. Durant, in the Los Angeles project, your agents had to send thousands of parcels to consumers because the system that the FDA and Customs relied on cannot handle the volume that you were now seeing. Is that right?

Ms. DURANT. That is correct.

Mr. DINGELL. Ms. Durant, has the United States Customs asked for guidance from FDA?

Ms. DURANT. Yes, sir. We have.

Mr. DINGELL. What has happened as a result? Have you received guidance?

Ms. DURANT. We have not received all of the guidance that we need to be effective in this area. However, we have been working together to come to practical guidance. This announcement today is very good news for us.

Mr. DINGELL. It is very clear, however, that the guidance that you have up until now is not adequate to address the problem. Is that not so?

Ms. DURANT. That is so.

Mr. DINGELL. Mr. Hubbard, isn't it the case that a U.S. citizen cannot walk into a pharmacy and purchase a controlled substance such as Darvon, Percocet, or Valium without a prescription, because these drugs pose inherent risks of addiction?

Mr. HUBBARD. That is correct.

Mr. DINGELL. All right. But, however, they can do the same thing in Mexico, purchase these very same drugs legally and bring them back into the United States as long as they are declared to U.S. Customs and have less than 50 tablets per drug. Is that right?

Mr. HUBBARD. I understand that is correct, that they can purchase it in Mexico. I will defer to DEA on the bringing back part.

Mr. DINGELL. Does anybody wish to deny that statement? Well, then we will let that stand for the record.

Now to all witnesses, do any of you have evidence that Oxycontin is available in Mexico? Is it being brought into the United States under the 50 dosage unit policy?

Do any of you have evidence that Oxycontin is available in Mexico and is being brought into the U.S. under the 50 dosage unit policy? That question to all members of the panel.

Ms. NAGEL. If I could try to address it. We have received information that Oxycontin is being smuggled.

Mr. GREENWOOD. Ms. Nagel, will you flip on your microphone?

Ms. NAGEL. Thank you. Excuse me. We have information specifically from Virginia that Oxycontin is smuggled in large quantities. We have no specific information about the 50-dosage-unit exemption being used to specifically bring in Oxycontin in any kind of organized manner.

Mr. DINGELL. Can you deny that Oxycontin is coming in through the 50-dosage exemption?

Ms. NAGEL. I have no specific information other than that individual, sir.

Mr. DINGELL. Now you are with DEA, are you not?

Ms. NAGEL. Yes, sir. I am.

Mr. DINGELL. And DEA doesn't know then whether Oxycontin is coming in or not. Is that right?

Ms. NAGEL. I said it is coming in, but whether it is coming in in any organized group, we have one case that we are aware of.

Mr. DINGELL. But you don't know whether it is coming in under the 50-unit exemption?

Ms. NAGEL. If it is, sir, it is coming in individual-by-individual case.

Mr. DINGELL. Okay. Can you deny that it is coming in?

Ms. NAGEL. No, sir.

Mr. DINGELL. Is there any reason to believe that it could not come in under this 50-unit exemption?

Ms. NAGEL. It would come in under the 50-unit exemption if the individual met all the requirements of the exemption.

Mr. DINGELL. If the exemption is not enforced, he comes in and shows 50 units, and walks through the Customs checkpoint. Is that right?

Ms. NAGEL. It is my understanding that can happen.

Mr. DINGELL. You say it could happen.

Ms. NAGEL. Yes, sir.

Mr. DINGELL. Is there any reason to believe that it has not happened?

Ms. NAGEL. No, sir.

Mr. DINGELL. Does the Customs have any evidence or comments on this particular point?

Ms. DURANT. We do have evidence that it is coming in under the 50 dosage units.

Mr. DINGELL. Under the 50 dosage unit?

Ms. DURANT. Yes.

Mr. DINGELL. Have you communicated that to DEA?

Ms. DURANT. We are gathering the data now.

Mr. DINGELL. You are gathering the data now.

Just quickly, perhaps the DEA can inform us. What is this Oxycontin? It is a very, very powerful substance, is it not?

Ms. NAGEL. Yes, sir. It is.

Mr. DINGELL. It is absolutely banned for sale or marketing in the United States. It is Schedule I, is it not?

Ms. NAGEL. No, sir. It is not. It is a Schedule II.

Mr. DINGELL. It's a Schedule II?

Ms. NAGEL. It is a legitimately manufactured pain medication. It is Oxycodone. It is a long-term release formulation that allows you to take it every 12 hours instead of having to take your pain medication every 4 or 3 hours. It is a Schedule II, sir, and it is legitimately manufactured and prescribed in this country.

Mr. DINGELL. And it is highly addictive, is it not?

Ms. NAGEL. Yes, sir. It can be highly addictive if misused.

Mr. DINGELL. I think my time has expired, Mr. Chairman. I thank you for your courtesy to me.

Mr. GREENWOOD. The Chair thanks the gentleman.

The Chair would note, Mr. Hubbard, that those of us who have served on this committee for more than 6 years still affectionately refer to Mr. Dingell as the Chairman, but we do not encourage our witnesses to do so.

Mr. DINGELL. Mr. Chairman, I would like to just make a brief observation. I don't care how the witnesses refer to me, as long as they answer the questions.

Mr. HUBBARD. I do apologize to the current chairman. Former Chairman Dingell was with us for so many years that it is difficult to—you know, habits do grow.

Mr. GREENWOOD. After I am here for 20 more years, you will get used to it.

The Chair recognizes the gentleman, Mr. Whitfield, for questioning.

Mr. WHITFIELD. Thank you, Mr. Chairman. I also would like to say that I was delighted to hear Mr. Hubbard outline his proposal to Secretary Thompson. With Mr. Greenwood, I certainly think that would be the most effective way to deal with this problem, because obviously the authorities do not have the manpower or the money to be very effective in preventing these drugs from coming in. So I am delighted that you all are going to recommend that, have already recommended it, and would like to reiterate what Mr. Greenwood said, that I know most of the people on this committee I am sure would look forward to working with you in implementing that.

On the drug Oxycontin, obviously it is an effective drug, pain killer, and it is legal when it is manufactured in the U.S., it is prescribed. I guess from my understanding, most of the problem relating to Oxycontin appears to be by theft, robbery, whatever. I mean is it a gigantic problem that it is coming into the country illegally?

Ms. NAGEL. If I could answer your question, sir. Our best information is that we have illegal prescribing, improper prescribing, pharmacy thefts, fraudulent prescriptions, doctor shopping. We do believe that Mexico could in fact be contributing to our problem.

When we received this information, we took some pretty aggressive steps. There is a single manufacturer of this narcotic. We have met with the company. We explained that we had information. We specifically had one case where people were smuggling it. As a result of our request, they have agreed to change the indicia of the drug. The drug that is now going to be exported to Mexico will appear different. If we then encounter it on the U.S. territories, I will then have the evidence and data I need to determine that it is being reimported.

Additionally, the company stopped shipping the 40 milligrams to Mexico. The 40 milligrams that were in-country in Mexico were moved from the border pharmacies. They were moved inland. So at this time, you can get the 10 milligrams and 20 milligrams.

If I am given the evidence and the data to demonstrate that in fact it is coming back in, I am prepared to meet with the company and look at some drastic measures. But what I need is the evidence. So we are hopeful, as everyone is gathering evidence, we have a national action plan that we have put forward where we are trying to gather the data and get our arms around the problem domestically and internationally. As we get the data and we can support the actions, we are more than prepared to move forward and take whatever action we can to limit the diversion and abuse in this country.

Mr. WHITFIELD. Now is Oxycontin exported to other countries as well?

Ms. NAGEL. Yes, sir. It is.

Mr. WHITFIELD. Okay. So that is being done legally. Basically what's happening, once it gets to these other countries, then it is illegally smuggled back into the U.S. to be used for purposes other than medicinal purposes?

Ms. NAGEL. At this point, we have information about Mexico. My concern was also that we could in fact experience the same thing from Canada. So at the same time, I asked the company to change the indicia of what goes to Canada. Fearing that my land borders would make me the most susceptible to having it come back. They are going to do that for me also. So that if I start to see it on the street, I will be able to identify the source.

I have no information of it coming back from any of the European countries or anywhere else.

Mr. BURR. Would the gentleman yield?

Mr. WHITFIELD. Yes, I would yield.

Mr. BURR. For one question. From what you have said, is Oxycontin only manufactured here?

Ms. NAGEL. There is one manufacturer, sir. They have plants in other places. But it is manufactured by one company.

Mr. BURR. But is the product that you speak of in Canada actually manufactured in the U.S., sold to Canada?

Ms. NAGEL. It used to be manufactured in the U.S. It is now manufactured in the U.K. It is exported from the U.K. to Canada. But the company has agreed to change the indicia as it is made in the U.K. so I can identify it if it comes back from Canada.

Mr. BURR. Thank you for that clarification.

Mr. WHITFIELD. Well, I appreciate you going into that explanation. Of course this is an important drug to a lot of cancer patients and others. So we certainly don't want to do anything to make it unavailable to them when it is prescribed legally in the U.S. But we also want to make sure that we minimize the illegal use of it. So it sounds like you all are making progress in that area.

Mr. Chairman, I will yield back the balance of my time.

Mr. GREENWOOD. The Chair thanks the gentleman, and recognizes the gentleman from Florida for 5 minutes for purposes of inquiry.

Mr. DEUTSCH. Thank you, Mr. Chairman. I want to take a little bit of a different tack to focus in terms of what we actually find, because again, having gone out to the Dulles facility, what is clear is that not everything that is coming in is a controlled II substance, controlled I substance. In fact, what appears, when we were there, is the vast majority of stuff that is coming in is either potentially supplements of some kind, foreign type supplements, or just homeopathic type things, or for that matter, prescription drugs, antibiotics, hypertension medication.

I think that is something that I think in the testimony and the questions up to this point has not been clear. I mean for all of us, and we can say it again and again, the volume of substances coming in is astronomical. I mean we are talking literally tens, hundreds of thousands, literally millions of substances coming in.

First, I mean if specifically I guess to Ms. Durant, would you sort of contradict or would you confirm what I just said in terms of the volume of the stuff coming in?

Ms. DURANT. The volume is astronomical.

Mr. DEUTSCH. Right. But the types, if you would categorize.

Ms. DURANT. The types are—I have looked at the lists of things in these various operations. The types are mixed. You are correct. There are some herbal drugs. There are some cardiovascular medications. But there are also a lot of steroids and narcotics and pain-killers, and those sorts of things.

Mr. DEUTSCH. Right. Again, we were only out there for 1 day, although they did prepare for our visit by doing a sort beforehand. But I think what is important to note is that again, we are talking about the millions. We really literally are talking about millions of substances coming in.

I think what was clear from Chairman Dingell's comments and from the questioning, and I think what really from the perspective, and again I know this is on C-SPAN as well, and hopefully they will get some coverage about this, is I don't think on the prescription drug side if it is an antibiotic or if it is a hypertension medicine, that someone really is legitimately looking for the least expensive pharmaceutical. No one wants to buy something that is going to kill them in that type of situation.

But I think one of the issues that again, you know it is hard for you to address, but I will tell you that one of the perspectives I have is that there are many Americans, millions of Americans, maybe even tens of millions of Americans who can not afford prescription drugs, who don't have prescription drug coverage, and for that matter, don't have medical coverage.

Mr. Hubbard, you made a great comment of your recommendation to the Secretary in terms of not allowing anything for anyone unless they have a medical doctor's direct supervision. Great theory if we have universal coverage. I mean I hope that you add in your recommendation, obviously I am being a little bit facetious in this, but that you add that the administration also support universal healthcare coverage for all Americans so that all Americans will have the opportunity to have physicians prescribe them drugs, and then have the supervision of those physicians for those drugs.

But until we get to that point in time, that is not America. I mean that is not America. I mean America is a country with literally tens of millions of Americans, working Americans, who get up in the morning every morning and go to work and work hard and support their families, do not have let alone doctor coverage, let alone prescription drug coverage.

So in the real world, and one of the things that we haven't done enough of, and again looking at the prescriptions and looking at what is coming in in the tens of thousands, and the hundreds of thousands of prescription drugs, not Schedule II, and again I am not discounting the Oxycontin phenomenon, which is a very, very serious issue. But I would assume that the percentage of the drugs coming in at that is a relatively small percentage. Yes, we found steroids. Yes, we found Ecstasy. But in terms of the volume, if you were there with us, if you spent time looking at it, it is a small percentage. It might be 5 percent. It might be less of the overall volume. So these are normal prescriptions.

I guess that is the question that I am saying to you, is maybe we are looking at this the wrong way. Maybe what we are really looking at is absolutely that 5 percent is really significant. All right? But the 95 percent very well might be hardworking, legitimate Americans who can not afford to go to a doctor to get a prescription, but are self-medicating. The answer that you gave is a simple answer, it would stop this completely. But what do you say to those people that can not afford going to the doctor, let alone paying a normal prescription? I mean I am asking you as a question because you are making that recommendation to the Secretary.

Mr. HUBBARD. First, I am sure the Secretary shares your concern about the availability of prescription drugs to all Americans. It is virtually impossible to differentiate here, the diversity is so great. There is every sort of drug coming in.

The problem is many of them allege to be a perfectly fine, an allergy drug, in this case. But we don't know that. We do not know anything about it. All we know is it has a name on it. We don't know what is in it. You can not test a box of ten drugs. It costs between \$6,000 and \$15,000 to do what we call authenticity testing of drugs. So to have the taxpayer pay to test that little package would be obviously absurd.

So our fear is that it is an all or nothing thing, that you can not distinguish between all of these millions of little packages. There is just no way that we know of. I assure you, we have spent considerable effort in the last couple of years trying to assess what these things are and what we might be able to do to parse out the most dangerous, the less dangerous, whatever. We just do not know a way.

Mr. DEUTSCH. Again, I guess, and this is a final question because I know we are in a vote and my time is up as well. I mean there is no one who is in that legitimate category that wants to purchase a drug that does not have the right dosage, that is a counterfeit drug, that is a misdiagnosed drug, that is impure in terms of facility. Obviously none of this stuff is really safe. I mean I think we can all acknowledge that. We have no oversight of the facility in Thailand. We have no oversight of the gray market stuff. We have nothing.

One of the things about our system in America is when you go to a pharmacy you have it. FDA does a great job in terms of its oversight, in terms of that. There is a safety level unparalleled in the world, unparalleled in world history in terms of drugs in the U.S. No one wants to do that.

But I guess one of the things that I think of when I am looking at this is what is driving people to put themselves at risk, to put their families at risk, to put their children at risk. They are not doing it for fun. I mean they are doing it because they want to save money. There are people out there who are using the Internet to purchase prescription drugs which again, the sites are nice looking sites and the description of my colleague from Michigan very well might be that in Thailand it is a beautiful website, but it is a rat-infested hellhole that is producing this stuff in Thailand.

I mean we saw literally dozens of boxes that were clearly from the same location in Thailand. I mean it was clear that it just so happened we got a batch of drugs being sent from a facility in Thailand. We opened them with the Customs officials, and they were different drugs. They were prescriptions, prescription drugs that people were clearly self-medicating.

I guess I mean we would think that a meaningful drug benefit would deal with this. But I mean that is why I do not think it is as simple as you are saying. I think that you will find a lot of opposition in Congress just to ban this across the board, because in fact there are a great deal of legitimate people using this avenue, not out of choice, but almost out of desperation.

Mr. GREENWOOD. The Chair thanks the gentleman. We could also solve the universal healthcare problem by allowing auto body shops to set up surgical centers, but that would be pretty dangerous too.

We are going to recess now for this vote until 1. We will reconvene then. We thank the witnesses for their patience.

[Brief recess.]

Mr. GREENWOOD. The subcommittee will reconvene again. We thank the witnesses for their forbearance.

The Chair recognizes for 5 minutes for purposes of inquiry the gentleman, Mr. Burr.

Mr. BURR. I thank the chairman.

Mr. Hubbard, let me say to the FDA I was shocked at what you told us. I was pleasantly pleased though that the FDA had taken a very strong position on this, and I want to commend you and commend the agency because I think the problem is severe. I think it needed a drastic recommendation.

Let me ask you what the Secretary's response to the proposal has been so far.

Mr. HUBBARD. Well, we talked to him on Monday. I think he certainly understands the issue. But he wanted to have more opportunity to talk to us, to understand the risks, to understand the procedure. I think he feels he needs a little more information. We will be giving him that, I think very soon. Of course he will probably want to consult further within the administration as well.

Mr. BURR. How long will it take us to get some indication from the Secretary as to whether the agency will adopt this proposal?

Mr. HUBBARD. I can't tell you, Mr. Burr. That is his prerogative.

Mr. BURR. How urgent on behalf of the FDA does the FDA think this problem is?

Mr. HUBBARD. Well I think by the very fact that we have characterized the risk here as so great, we would call it pretty important. The Secretary and his staff, we have already had discussions with them. They are very attentive to this. This is not something where they can't find time to think about.

They do want to have information.

Mr. BURR. Ms. Durant, is the mail that is received at JFK higher in the number than it is received at Dulles?

Ms. DURANT. Yes, sir.

Mr. BURR. How many packages discussed in x-ray at JFK?

Ms. DURANT. Twenty to 30 times Dulles.

Mr. BURR. Do you x-ray all the packages at JFK?

Ms. DURANT. Not all of them at JFK.

Mr. BURR. What percentage?

Ms. DURANT. Ten to 15 percent.

Mr. BURR. Ten to 15 percent?

Ms. DURANT. About. I could get a better number for the record.

Mr. BURR. Let me state that we understand the constraints that Customs is under. We understand how difficult it is to operate in a policy that today is so loosely written whether you are any of the agencies that are up here. But if the Secretary needs a nudge on the urgency, we have seen the degree of the problem with just the 10 or 15 percent that we check. Think about the 85 percent that we are not.

The burden that is placed on Customs today is huge. My hope is that in that proposal they have got the ability when there is a drug shipment that comes in, to stamp "return to sender," and it is over with. It is out of their hands. It does not need the FDA to send somebody in. It does not need a letter to go to somebody. We need to eliminate that from the process so Customs can get to the next piece of the puzzle in their job responsibility.

Is this proposal, does it include all prescription drugs?

Mr. HUBBARD. Yes, it would, Mr. Burr, except for the exception I mentioned of the compassionate use.

Mr. BURR. Compassionate use.

Mr. HUBBARD. Now it would not include at this point the so-called walk-across folks that go to Canada or Mexico. There, we would like to think about that some more. There, you have a face-to-face interaction. The patient actually stands in front of a pharmacy and purchases a drug, say in Canada. There is an opportunity because of that to go back if there is a problem and find the source of the drug. There is an opportunity for FDA or Customs or others as the patient is coming back across the border, say the Canadian border, to be warned, to be given perhaps a slip of paper saying if you have bought drugs, you need to be——

Mr. BURR. Are they required when they cross in person to show a prescription for what they——

Mr. HUBBARD. I believe they are required to declare, but I will ask Ms. Durant to answer that.

Ms. DURANT. For the 50 dosage units, they are not.

Mr. BURR. They are not, are they?

Ms. DURANT. No.

Mr. BURR. In the next panel, panel three, Marvin Shepherd, the College of Pharmacy, University of Texas, will testify that he has just been to the border. He has seen Oxycontin packaged in blister packs, 50 pills, so that it meets the requirements not to be scrutinized as you cross the border. They are just sending it across day-in and day-out. I hope that the DEA will in fact listen to his testimony because it is happening. It will continue to happen. We won't stop it with that exception to the proposal that you have in fact made to the Secretary. So I would ask you to really go back and look at that. We do not want to just narrow the problem to two borders that we already have significant problems with.

Let me ask you, would it include over-the-counter products?

Mr. HUBBARD. Generally, over-the-counter products like this are also unapproved. We have given them less attention because they are viewed generally as safe, but yes, it would.

The theory is that any drug bought in another country that is unapproved can not be safe.

Mr. BURR. Customs would not have to make a determination?

Mr. HUBBARD. That is correct, Mr. Burr.

Mr. BURR. Let me ask you on one other subsection, animal drugs.

Mr. HUBBARD. Animal drugs?

Mr. BURR. Yes, sir. Currently in this country for animals, we access quite a few drugs from Europe and from Canada. Do you see animal drugs included under this or do you look at an exception for that?

Mr. HUBBARD. To be honest, we have not had any discussion about that. I am not aware that that is a problem, but I will be glad to check that out and get back to you.

Mr. BURR. Granted, animal drugs are not in the volume of human drugs. But I think when you look at the access that they need from international markets, it is much greater than the access that we need for human drugs. But I would ask you to look at that.

Does Mexico have an equivalent to the FDA?

Mr. HUBBARD. Yes, they do. But obviously different countries have different levels of regulation.

Mr. BURR. Do we have a harmonization agreement with the approval process with the Mexican agency that is the equivalent?

Mr. HUBBARD. No, we do not.

Mr. BURR. Have we been able to harmonize the standards on drug approvals with the EU yet?

Mr. HUBBARD. We made great progress in a number of areas of drug testing and development, yes. We are not 100 percent there, but that is certainly the goal, to make them the same in both EU and here. The Canadians are involved in that as well.

Mr. BURR. But the reality is that we don't even have the confidence in their systems that we can interchange the standards that we use even in the European Union. That is correct, isn't it?

Mr. HUBBARD. That is correct. Although perhaps some day under the constructs that are being envisioned, that may be possible.

Mr. BURR. I would like to read just a piece out of your testimony. I will comment on it and let you comment as well.

"The FDA has not officially permitted the importation of foreign versions of U.S. approved medications, even if sold under the same name." "The FDA has not officially permitted the importation of foreign versions of U.S. approved medications." That one statement right there would say that the only products that could the under even today's standard come back in are products that were manufactured in the United States.

Mr. HUBBARD. Or in a foreign plant that was approved and inspected by the FDA.

Mr. BURR. Well, this says, "The FDA has not officially permitted the importation of foreign versions of U.S. approved medications even if sold under the same name." That would be products manufactured.

Mr. HUBBARD. No. I think what that refers to, let's say Viagra might be made in Pfizer's Irish plant, which is approved by FDA and it might be made in Pfizer's—I am making up this example, of course—Spanish plant that is the drug that's sold in Europe and Asia. We might not have inspected and approved that plant. So the Irish plant could bring the drug to the United States and the Spanish plant could not.

Mr. BURR. Let me read one other piece. "Therefore, unapproved drugs and reimported approved medications may be contaminated, sub-potent, super-potent, or counterfeit." Given that that is part of the FDA's testimony today, let me just ask you one question. How could the FDA sit silent over the past 2 years when the debate of reimportation took place in the Congress of the United States? When today that is a great threat in your testimony, reimportation of approved medications contaminated, sub-potent, super-potent, and counterfeit. How could the FDA sit silent during that debate?

Mr. HUBBARD. I think we have been consistent in expressing our concern about the safety of these products during the debate last year about the bill that passed Congress to allow large shipments, commercial shipments to come in. I do believe, Mr. Burr, we have been fairly consistent in saying that the system that Congress created in 1938 serves the public very well. It is a fairly rigid system. These sorts of drugs from other countries, whether they are large commercial shipments or these personal amounts, can not be as easily assured of safety.

Mr. BURR. Given your proposal to the Secretary relevant to this issue that we are here talking about today, what would the FDA's position be to this committee if the Congress were considering reimportation legislation like we saw last year?

Mr. HUBBARD. I think we would be saying the same thing to the committee that we said last year to the various Members of Congress, which is we are very concerned that a system, if designed to be a different system than the current system, poses risks and we can not be assured that we could successfully implement such a system and bring in safe drugs because we do not have the same level of confidence about where it was manufactured, and how it was manufactured, and by whom it was manufactured, that we have under the current system.

Mr. BURR. Let me suggest if you get asked the question again, that you give the response of the recommendation that you made to the Secretary as boldly and forcefully as you said it. Today we have an unwritten policy for products coming in, if they meet a certain dose—and you have said there is no way for us to do this. We need to shut it down. There is no way you can look at this and say we have got to shut it down, the problem is so great, and look over here and try to make an issue of reimportation work.

We can not ask Customs to determine where it was made, where it came from, how it was stored, whether it is counterfeit, whether it is adulterated. You know, I said to some of my colleagues I hoped everybody read the New York Times article this week about three fake drugs are found in U.S. pharmacies, hormone drugs, well-known manufactured companies that their product had been contaminated on the shelf with counterfeit product. Because of the great work of the FDA and their ability to track from wholesaler to wholesaler to wholesaler, I think they have got a pretty good handle on how this happened. Does it eliminate it again? No.

But the reality is that even the shelves of the pharmacies that we go to in this country are susceptible to having contaminated products with the absolute gold standard in the world as far as drug approval and review.

My hope is that we will not open that system up to the ability for it to deteriorate with something that sounds good like reimportation or something that sounds good like personal use. We ought to always be the compassionate country that has a compassionate use exception to the standard. But for God's sake, let us have a standard. I think that is the only hope of this committee.

Mr. Chairman, I thank you. I yield back.

Mr. GREENWOOD. The Chair thanks the gentleman, and recognizes Mr. Stupak. Before doing so, I understand Dr. Leshner has a pressing need to leave and excuses him from further testimony.

Mr. Stupak?

Mr. STUPAK. Thank you, Mr. Chairman.

In response to Mr. Burr's question, Mr. Hubbard, you indicated that the FDA is consistently concerned. With all due respect, consistently you have been doing nothing about this problem. I'm going back to 1996 when Dr. Shepherd gave you a copy of his report about these drugs coming across the Mexican border, and nothing has happened.

We hear from the Rodes today that you go there and you got their information in July of last year. Again, they have heard nothing back from the FDA. At least the Customs has agreed to at least meet with them. Can you make a commitment to the Rodes you are at least going to meet with them and tell them what is going on? They lost their son. It is a year later, and you don't even respond to them?

Mr. HUBBARD. I spoke to Reverend Rode before the hearing, Mr. Stupak, and expressed my condolences, and assured him that the most vigorous investigation was underway. The question of feedback to him is not one that I can answer well. These investigations are kept, for obvious reasons, pretty quiet because we have to do that.

Mr. STUPAK. I am not here asking for an answer. I am saying at least show the people some respect and get back with them. You met with their daughter. You took the drugs. They don't even know what it is. You have done basically nothing. They had to come here to Washington, D.C. to figure out what you are doing, if you are doing anything.

Mr. HUBBARD. I told, Mr. Stupak, that we have talked to them and given them some feedback. But I will be glad to confirm that.

Mr. STUPAK. That is not what they are telling us.

Mr. HUBBARD. Yes. I understand.

Mr. GREENWOOD. Would the gentleman yield?

Mr. STUPAK. Yes, I would, Mr. Chairman.

Mr. GREENWOOD. Very briefly. We would appreciate it if FDA and Customs would arrange—we will arrange for the staff if you would brief interested members of this subcommittee on the status of that investigation in a confidential matter. I think that would be useful. I would like you to take that back to your offices.

I yield back to the gentleman.

Mr. STUPAK. Thank you.

This recommendation you made to Secretary Thompson on Monday, is that in writing?

Mr. HUBBARD. Well, yes. As well as we have met with him and with his staff more than once. There will be further discussions.

Mr. STUPAK. Will you submit that for this committee?

Mr. HUBBARD. I will certainly determine if we can do that, yes.

Mr. STUPAK. How long will it take to make this recommendation become a reality?

Mr. HUBBARD. Well, as I said, if we——

Mr. STUPAK. No, no. I want some answers.

Mr. HUBBARD. Okay. I hate to say it, but have to throw it back to Congress because we can't do this.

Mr. STUPAK. Throw it back to Congress? You need us to do it?

Mr. HUBBARD. I'm sorry.

Mr. STUPAK. Do you need us to do it? Was it quicker for us to do it or to wait for the Secretary?

Mr. HUBBARD. We explained two avenues, Mr. Stupak, to implement this. One is to write a regulation.

Mr. STUPAK. Write a regulation, get it approved, you have got to publish it in the Register, 180 days comment period. We are at least a year away, are we not?

Mr. HUBBARD. If we do a regulation, that is correct.

Mr. STUPAK. And if Congress moves, good grief, it could be 5 years away. Right?

Mr. HUBBARD. The only alternative is for us to try to accept these things now, and I do not think we can do that.

Mr. STUPAK. My impatience not only goes back to 1996 Dr. Shepherd, but I will start here with January 6, 2000, letters from Commissioner of Customs, letters back and forth not only from this committee, but from Customs and others, asking you to address this issue. We get back a lot of nice letters saying we are concerned, we are consistently going to do something, but nothing ever happens. I am trying to pin you down to a timeframe because this can not go on.

In the recommendation you made to the Secretary, the same recommendation the chairman and the rest of us made to you at Dulles, the same recommendation we made to you before we went to Dulles when we had a briefing. We are getting tired of making recommendations to you. You are the agency, lead agency who has to take the bull by the horns here, and you are not.

So when I say, with all due respect, consistently doing nothing, for some of us it is getting a little frustrating.

Mr. Chairman, I move that these letters from Customs and others back and forth to the FDA on this matter be made part of the record.

Mr. GREENWOOD. Without objection, they will.

Mr. STUPAK. I also move that Dr. Shepherd's 1996 study to the FDA and Customs, the rest of it, also be made a part of the record.

Mr. GREENWOOD. Without objection.

[The information referred to follows:]

**THE COMMISSIONER OF CUSTOMS****WASHINGTON, D.C.**

January 6, 2000

Ms. Jane Henney, M.D.
Commissioner of Food and Drugs
5600 Fisher Lane
Rockville, Maryland 20857

Dear Ms. Henney:

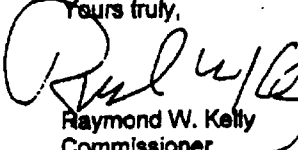
Over the years, our respective agencies have worked closely together on issues of great importance to our Nation. Recently, our enforcement efforts have focused on the interdiction of pharmaceuticals imported into the United States. These importations occur through international mail, express consignment facilities, and accompanying international travelers.

In light of the recent increase in the number of seizures and the dramatic growth in the use of the Internet to order pharmaceuticals illegally, Customs needs additional assistance from you. I am requesting your agency provide us with a written national standard for the interdiction of these products, as well as requirements for the legal importation of pharmaceuticals. Secondly, we need Food and Drug Administration (FDA) personnel to be responsive at our International Mail Branches and Express Consignment facilities. Enough FDA resources are needed so that upon request, determination of admissibility of pharmaceuticals can be made within one business day.

Finally, when Customs detains a pharmaceutical shipment, which FDA then releases, Customs needs a written release certification signed by an FDA official.

With this additional assistance, both agencies would strengthen their effectiveness in preventing illegal importation of these products. I propose that we develop a Memorandum of Understanding between us to clarify our respective responsibilities. I look forward to working with you on this important issue. Please call me if you wish to discuss this further.

Yours truly,


Raymond W. Kelly
Commissioner



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

February 18, 2000

—Mr. Raymond W. Kelley
Commissioner
U.S. Customs Service
1300 Pennsylvania Avenue, N.W.
Washington, D.C. 22029

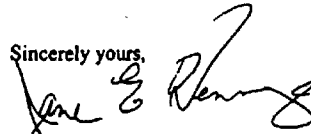
Dear Mr. Kelly:

Thank you for your January 6, 2000, letter acknowledging our respective agencies' efforts to benefit the public health and safety of our nation. Indeed, our agencies have enjoyed many successes as a result of joint U. S. Customs Service (USCS) and Food and Drug Administration (FDA) operations and initiatives. The ability of our agencies to work together effectively is demonstrated by the ongoing cooperation and collaborative efforts of personnel from both agencies in the development of the Presidential Food Safety Initiative. FDA remains fully committed to continuing its cooperative efforts with USCS.

FDA is currently evaluating its policies and procedures for personal importation of FDA-regulated products, including pharmaceuticals, which may be imported through mail facilities or express consignment facilities, as well as by individuals through border crossings and international travel. After FDA completes this evaluation, I propose that our agencies meet to develop appropriate enforcement strategies. At that time, we could also determine the need to develop another Memorandum of Understanding. I expect FDA will be prepared to meet with USCS on the issue of imported pharmaceuticals in the near future. Please identify a member of your staff as the contact for arranging such a meeting.

I am very pleased that you share my concern about the public health issue of Internet sales of prescription pharmaceuticals. With our continued cooperation, I am confident our agencies can help protect consumers from unsafe or ineffective drugs. I look forward to working with you on this important issue.

Sincerely yours,


Jane E. Henney, M.D.
Commissioner of Food and Drugs

TLH:INTERNET (selling drugs online)
 HEALTH:FDA:Drugs-(same as above)

Cy: 2+5

ONE HUNDRED SIXTY CONGRESS

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**U.S. House of Representatives
 Committee on Commerce**

Room 2125, Rayburn House Office Building
 Washington, DC 20515-6115

February 28, 2000

The Honorable Raymond Kelly
 Commissioner
 United States Customs Service
 1300 Pennsylvania Avenue, N.W.
 Washington, D.C. 20229

Dear Commissioner Kelly:

We appreciate your providing Committee staff with the opportunity to visit the U.S. Customs' mail inspection facility at Dulles International Airport in connection with our investigation into the shipment into the United States of pharmaceuticals purchased over the Internet. As your agency clearly recognizes, these Internet sites have multiplied dramatically over the past year. As these activities will likely increase in the near future, demands on existing governmental resources, including your agency, will only increase.

According to your inspectors, illegal pharmaceuticals make up the bulk of illegal contraband detained for cause at the Dulles facility. Many of these originate from online pharmacy transactions. We also understand that most of these name-brand products detained cannot be verified as authentic, or even as products made in accordance with U.S. Food and Drug Administration standards. Further, we understand that of those pharmaceuticals detained, a significant amount arrive with no information (such as dosage instructions, warnings of potential drug interactions, side effects, etc.) or even proof that a licensed physician or pharmacist was involved in the transaction. In fact, inspectors report that many of the pharmaceuticals simply arrive in plastic ziplock bags with nothing indicating the bags' contents. Such practices place the public at considerable risk, and are clearly inconsistent with the various U.S. laws and regulations designed to protect consumers from dangerous or ineffective drugs.

As you may know, we have been investigating a number of issues relating to this problem over the past year-and-a-half, including what actions the Federal Government is taking or should take, and what resources, including both personnel and technologies, are required to do the job. We understand that some agents and inspectors already feel overwhelmed by this problem. Consequently, we would appreciate your assistance in providing us with the following information:

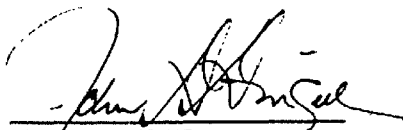
The Honorable Raymond Kelly
Page 2

- (1) What resources does your agency currently dedicate to stopping the shipment of illegal pharmaceuticals into the U.S. by Internet pharmacies, and by what means? How significant does your agency estimate this problem to be (by volume seized, for example)? What future resource needs do you estimate your agency will need to address this matter? Finally, if any additional resources are needed, please indicate specifically how they would be used.
- (2) Please provide us with a brief description of the types of pharmaceutical products now being seized by inspectors at the Dulles mail facility. For example, of the packages detained, please provide: (a) the types of pharmaceutical products being found; (b) the frequency and quantity at which you are finding them; and, (c) the brand name and manufacturer (if known) of the major products.
- (3) If your agency has determined or suspects that any of the products identified in your response to question number 2 are counterfeit, please provide the basis for your determination or suspicion. If your agency has discovered counterfeit pharmaceuticals, please indicate if routine, from where such products are being sent.
- (4) Generally, of the pharmaceutical products detained by your agency, please indicate, if possible, the percentage of such products that are being shipped into the U.S. via an Internet pharmacy transaction.

Finally, we are interested in arranging an additional visit to the Dulles mail facility for members of the Oversight and Investigations Subcommittee. We would appreciate your assistance in arranging such a visit at a mutually agreeable date within the next several weeks.

We appreciate the effort by your agency on this important public health matter, and continue to look forward to working with you in the future. Your timely attention to this response is also appreciated. If you have any questions about this matter, please feel free to contact us directly or have your staff contact Mr. Christopher Knauer of the Commerce Committee Democratic staff at (202) 226-3400.

Sincerely,



JOHN D. DINGELL
RANKING MEMBER
COMMITTEE ON COMMERCE



RON KLINK
RANKING MEMBER
SUBCOMMITTEE ON OVERSIGHT
AND INVESTIGATIONS

The Honorable Raymond Kelly
Page 3

cc: The Honorable Tom Bliley, Chairman
Committee on Commerce

The Honorable Fred Upton, Chairman
Subcommittee on Oversight and Investigations

The Honorable Michael Bilirakis, Chairman
Subcommittee on Health and the Environment

The Honorable Sherrod Brown, Ranking Member
Subcommittee on Health and the Environment

The Honorable Jane E. Henney, M.D., Commissioner
Food and Drug Administration



U.S. Customs Service

1300 Pennsylvania Avenue, N.W. Washington, D.C. 20229
202-927-2001 Fax 202-927-1650

Commissioner of Customs

September 5, 2000

Jane E. Henney, M.D.
Commissioner
United States Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Henney:

I regret that a previous commitment prevented me from seeing you during your recent visit to Customs to meet with Assistant Commissioner Bonni Tischler. I am told that the meeting on August 11, 2000, which included members of the respective staffs, was productive. However, I am still somewhat concerned that the issues raised in my letter to you dated January 6, 2000, concerning pharmaceuticals purchased over the internet and imported via mail or express couriers are still not adequately resolved.

In that letter, I requested that your agency provide us with "written national standards for the interdiction of these products, as well as requirements for the legal importation of pharmaceuticals." In addition, I requested "Food and Drug Administration (FDA) personnel to be responsive at our International Mail Branches and Express Consignment facilities." It is important that enough FDA resources are made available to us so that, upon request, determination of admissibility of pharmaceuticals can be made within 1 business day. Lastly, it was requested that, when "Customs detains a pharmaceutical shipment, which FDA then releases, Customs needs a written release certification signed by an FDA official."

I am extremely encouraged by the agreement reached at the August 11th meeting to convene a joint Customs/FDA task force to analyze and examine current operational procedures and best practices to develop a uniform enforcement policy for national implementation. This approach is consistent with your written response to me dated February 18, 2000 (copy enclosed). Although I applaud this effort, until such time that those uniform national instructions are developed, it is still critical that Customs receive interim guidance as requested in my January 6, 2000, letter (copy enclosed).

TRADITION

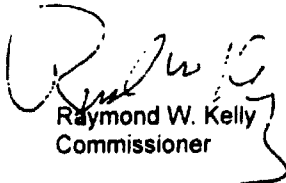
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- 2 -

I appreciate the cooperation shown by you and your staff; and I am confident that, together, we will achieve success in the pursuit of our mutual objectives. If we may be of further assistance, please call me or have a member of your staff contact Mr. Paul K. Schwartz at (202) 927-0667.

Yours truly,



Raymond W. Kelly
Commissioner

Enclosures



U.S. Customs Service

1000 Pennsylvania Avenue, N.W. Washington, D.C. 20529

SEP 12 2000

Mr. Dennis E. Baker
Associate Commissioner, Regulatory Affairs
United States Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Mr. ~~Baker~~ ^{Demo}:

It was my distinct pleasure to meet with you and your staff on Friday, August 11, 2000. The issues we addressed in our meeting: pharmaceuticals purchased over the Internet, the Food Safety Report for the President, the impact of the International Trade Data System (ITDS) on the Customs/FDA interface, and our mutual outreach efforts to the public represent high priorities for both Customs and the FDA. Please allow me to recap the meeting.

The first item on the agenda was pharmaceuticals purchased via the Internet. There has been a great increase in the volume of both controlled and non-controlled pharmaceuticals purchased over the Internet. Subsequently, these goods enter the United States by mail or express consignment. It was mutually agreed that to effectively enforce the laws and regulations that govern these articles, national, uniform enforcement procedures must be developed and implemented. To realize this objective, we agreed to develop a Customs/FDA Joint Task Force. The purpose of this task force will be to analyze and examine current operational procedures and best practices. As a result of this analysis, the task force will develop a uniform enforcement policy for national implementation. Mr. Paul Schwartz, of my staff, has met with Mr. Joe McCallion, of your staff, to begin this initiative. It is my understanding that progress is being made in setting up the pilot in Los Angeles. It is also my understanding that the possibility of instituting a pre-arrival FDA approval system to replace the present post-arrival system is being given serious consideration. I applaud this approach since it will clearly address the issue of insufficient availability of local FDA officials to U.S. Customs.

The second item on the agenda was the FDA/Customs Food Safety Report for the President. As you will recall, the President approved the report in December 1999, however, several enforcement issues remain unresolved. Customs requires guidance from the FDA to effectively enforce the affected laws and regulations. It was agreed that the FDA will provide the necessary information to Customs to satisfy these requirements.

TRADITION

SERVICE

HONOR

- 2 -

The third item on the agenda was the impact of the International Trade Data System (ITDS) on the FDA. ITDS is slated to be the Federal government's electronic "collector" of import and export data. Customs is committed to the ITDS concept, and we are working hard towards a successful pilot. However, we agree there are many unanswered questions. I suggest a follow-up meeting on this topic be scheduled if you want to discuss this matter further.

The fourth and last item on the agenda was the outreach efforts by Customs and the FDA to the public. With the recent highly publicized issues involving personal pharmaceutical importations, the close working relationship between Customs and the FDA is essential to safeguard the American public. A strong, joint outreach program to ensure that the public gains a better understanding of the issues and implications associated with the importation of prescription drugs for personal use will increase our effectiveness in protecting the public from unsafe, unapproved counterfeit drugs. It was agreed that the Offices of Public Affairs, for both agencies, would work in concert to develop a unified message to the public. I have asked Mr. Paul Schwartz, of my staff, to contact our Public Affairs Office to advise them of this effort and to begin the communications process with your Public Affairs Office. It is my understanding that this process has already begun.

Once again, it was my pleasure to meet with you and your knowledgeable staff. I am confident that, together, we will successfully address our mutual concerns. If there are any other issues that you feel still need to be discussed, please call me or have a member of your staff contact Mr. Paul K. Schwartz at (202) 927-0667.

Sincerely,



Bonni G. Tischler
Assistant Commissioner
Office of Field Operations

HFC-1
Urban

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

October 11, 2000

Raymond W. Kelly
Commissioner
U.S. Customs Service
1300 Pennsylvania Avenue, N.W.
Washington, D.C. 20279

Dear Commissioner Kelly:

Thank you for your letter of September 5. I regret that we were unable to meet when I visited the Customs Service on August 11, but I appreciate the courtesies which were extended by your staff.

I understand your concern with the importation of pharmaceuticals purchased over the Internet and the need for Customs personnel to have access to FDA's "written national standards for the interdiction of these products, as well as requirements for the legal importation of pharmaceuticals." This is an issue that FDA has struggled with for many years. As you may know, the Federal Food, Drug, and Cosmetic Act does not contain any exemption for products imported for personal use; it provides for the refusal of admission of violative pharmaceuticals, regardless of the identity of the importer. For many years, FDA has exercised its enforcement discretion as a "humanitarian option" to allow individuals to import unapproved drugs for personal use under certain specified conditions. These are spelled out in FDA's Coverage of Personal Importations (copy enclosed and located on the Internet at http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html). This document represents FDA's current national guidance on personal importation.

At our August 11 meeting, we agreed that there has been a great increase in the volume of both controlled and non-controlled substances purchased over the Internet and entering the United States by mail or express consignment. We mutually agreed that to effectively enforce the laws and regulations that govern these articles, national, uniform enforcement procedures must be developed and implemented. To achieve this objective, we agreed to develop a Customs/FDA Joint Task Force. The purpose of this task force will be to analyze and examine current operational procedures and best practices. As a result of this analysis, the task force will develop a uniform enforcement policy for national implementation.

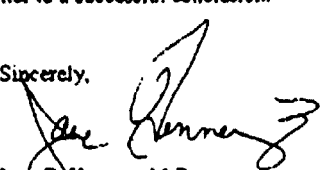
I share your concern about FDA's level of staffing at International Mail Branches and the methods which FDA employs to screen mail entries and notify Customs of our admissibility decisions. FDA supports the notion that the U.S. Postal Service should

Page 2 - Raymond W. Kelly

automate the declarations and manifests for international mail. Currently, mail entry review is a resource-intensive manual process. Automation would leverage some human resource needs and improve admissibility decisions. Any tracking would be a result of the U.S. Postal Service automation. I believe it is premature to commit to specific FDA resources and procedures for improving coverage at the international mail facilities. FDA will reassess the resources needed following the joint FDA/Customs mail facility pilot. I look forward to seeing the results of that very important project. This collaborative effort should result in the establishment of a working model that is effective, both from a cost perspective and in protecting the nation's public health.

We appreciate the assistance you have offered on this issue and your willingness to participate in this joint Customs/FDA Task Force. With the best efforts of both of our agencies, I am sure that we can bring this matter to a successful conclusion.

Sincerely,


Jane E. Henney, M.D.
Commissioner of Food and Drugs

*New
international
mail facility*

Enclosure

SUBCHAPTER

COVERAGE OF PERSONAL IMPORTATIONS

PURPOSE

To provide guidance for the coverage of personal-use quantities of FDA-regulated imported products in baggage and mail and to gain the greatest degree of public protection with allocated resources.

BACKGROUND

Because the amount of merchandise imported into the United States in personal shipments is normally small, both in size and value, comprehensive coverage of these imports is normally not justified. This guidance clarifies how FDA may best protect consumers with a reasonable expenditure of resources.

There has always been a market in the United States for some foreign made products that are not available domestically. For example, individuals of differing ethnic backgrounds sometimes prefer products from their homeland or products labeled in their native language to products available in the United States. Other individuals seek medical treatments that are not available in this country. Drugs are sometimes mailed to this country in response to a prescription-like order to allow continuation of a therapy initiated abroad. With increasing international travel and world trade, we can anticipate that more people will purchase products abroad that may not be approved, may be health frauds or may be otherwise not legal for sale in the United States.

In addition, FDA must be alert to foreign and domestic businesses that promote or ship unapproved, fraudulent or otherwise illegal medical treatments into the United States or who encourage persons to order these products. Such treatments may be promoted to individuals who believe that treatments available abroad will be effective in the treatment of serious conditions such as AIDS or cancer. Because some countries do not regulate or restrict the exportation of products, people who mail order from these businesses may not be afforded the protection of either foreign or U.S. laws. In view of the potential scale of such operations, FDA has focused its enforcement resources more on products that are shipped commercially, including small shipments solicited by mail-order promotions, and less on those products that are personally carried, shipped by a personal non-commercial representative of a consignee, or shipped from foreign medical facility where a person has undergone treatment.

PERSONAL BAGGAGE

FDA personnel are not to examine personal baggage. This responsibility rests with the U.S. Customs Service. It is expected that a Customs officer will notify their local FDA district office when he or she has detected a shipment of an FDA-regulated article intended for commercial distribution (see GENERAL GUIDANCE below) an article that FDA has specifically requested be detained, or an FDA regulated article that appears to represent a health fraud or an unknown risk to health.

When items in personal baggage are brought to FDA's attention, the district office should use its discretion, on a case-by-case basis, in accordance with the guidance provided under GENERAL GUIDANCE below, in deciding whether to request a sample, detain the article, or take other appropriate action.

MAIL SHIPMENTS

FDA personnel are responsible for monitoring mail importations. It is expected that a Customs officer from the Customs Mail Division will examine a parcel and will set it aside if it appears to contain a drug, biologic, or device, an article that FDA has specifically requested be held, or an FDA-regulated article that appears to represent a health fraud or unknown risk to health.

FDA should audit those parcels set aside by Customs in accordance with the guidance provided under **GENERAL GUIDANCE** below, using the following procedures:

Prepare a Collection Report for each parcel sampled. Generally, a physical sample is not required on mail importations because a documentary sample (for example, labeling, labels and inserts) will be sufficient for most regulatory purposes. If a physical sample is needed, collect only the minimum necessary for analysis by the laboratory. The remaining portion should not be removed from the custody of the Customs Mail Division.

Importations detained in accordance with this guidance should be held by Customs until they are either released or refused entry. Attached as guidance are two specimen letters that may be sent with the Notice of Detention and Hearing when a parcel is detained. (See Exhibit 9-3 for use in general mail importations and Exhibit 9-4 for use in unapproved drug or device mail importations).

On occasion, products detained by FDA will be mixed with non-FDA-regulated products. When we refuse admission of the FDA-regulated portion, any request for the release of the non-FDA-regulated portion should be referred to the Customs Mail Division with a Notice of Refusal of Admission covering the detained article. Final disposition of all merchandise, including the destruction of detained merchandise, is the responsibility of Customs.

GENERAL GUIDANCE

The statements in this chapter are intended only to provide operating guidance for FDA personnel and are not intended to create or confer any rights, privileges, or benefits on or for any private person.

FDA personnel may use their discretion to allow entry of shipments of violative FDA regulated products when the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user. Even though all products that appear to be in violation of statutes administered by FDA are subject to refusal, FDA personnel may use their discretion to examine the background, risk, and purpose of the product before making a final decision. Although FDA may use discretion to allow admission of certain violative items, this should not be interpreted as a license to individuals to bring in such shipments.

Commercial or Promotional Shipments

Commercial and promotional shipments are not subject to this guidance. Whether or not a shipment is commercial or promotional may be determined by a number of factors including, for example, the type of product, accompanying literature, size, value, and/or destination of the shipment. FDA personnel may also consider whether an importation of drugs or medical devices is a commercial shipment by evaluating whether the article appears to have been purchased for personal use or whether the quantity suggests commercial distribution (i.e., the supply exceeds what one person might take in approximately three months). Commercial shipments generally include shipments other than those products that are personally carried, shipped by a personal non-commercial representative of a consignee, or shipped from a foreign medical facility where a person has undergone treatment.

Products Other than Drugs and Devices

Many products other than drugs, biologics, and devices that individuals seek to import in personal quantities do not pose a significant health risk although they appear to be violative and may be the subject of an import alert or automatic detention based on standards violations, filth, and/or labeling problems. When such items are brought to FDA's attention by Customs, it may be appropriate for FDA personnel to use their discretion to "Release with Comment" and advise the importer of the agency's concerns. FDA personnel should be alert to and should detain those products that do pose a

significant health risk.

Drugs, Biologics, and Devices

When personal shipments of drugs and devices that appear violative are brought to FDA's attention by Customs, FDA personnel will use their discretion to decide on a case by case basis whether to detain, refuse, or allow entry of the product. Generally, drugs and devices subject to Import Alerts are not amenable to this guidance. Devices to be used by practitioners for treating patients should not be viewed as personal importations subject to this chapter. Drugs subject to Drug Enforcement Agency (DEA) jurisdiction should be returned to Customs for handling.

In deciding whether to exercise discretion to allow personal shipments of drugs or devices, FDA personnel may consider a more permissive policy in the following situations:

1. when the intended use is appropriately identified, such use is not for treatment of a serious condition, and the product is not known to represent a significant health risk; or
2. when a) the intended use is unapproved and for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means; b) there is no known commercialization or promotion to persons residing in the U.S. by those involved in the distribution of the product at issue; c) the product is considered not to represent an unreasonable risk; and d) the individual seeking to import the product affirms in writing that it is for the patient's own use (generally not more than 3 month supply) and provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the product, or provides evidence that the product is for the continuation of a treatment begun in a foreign country.

If there are any questions about the application of these factors to any product, the product should be detained and FDA personnel should consult with the appropriate headquarters office.

When a shipment is not refused entry, FDA personnel may consider issuing a "Release with Comment" and, as appropriate, advise the recipient that 1) the drug (or device) that has been obtained for personal use appears to be unapproved in the United States; 2) the drug (or device) should be used under medical supervision; 3) FDA may detain future shipments of this product; and 4) the patient's physician should consider for example, enrolling the patient in an Investigational study or applying for Investigation New Drug (IND), Compassionate IND, or Treatment IND exemption.

IMPORT ALERTS

FDA personnel should recommend to the Division of Import Operations and Policy (HFC-170) the issuance of an import alert if they encounter:

1. personal importation of products that represent either a direct or indirect health risk; or
2. the promotion of unapproved foreign products for mail order shipment; or repeated importation of products that represent fraud*.

*(See Compliance Policy Guides Manual, Section 120.500, "Health Fraud - Factors in Considering Regulatory Action" (CPG 7150.10))



U.S. Customs Service

1300 Pennsylvania Avenue, N.W. Washington, D.C. 20229

NOV 22 2000

Dennis E. Baker
Associate Commissioner, Regulatory Affairs
United States Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Mr. Baker:

In a letter to FDA Commissioner Dr. Jane Henney dated September 5, 2000, Customs Commissioner Raymond Kelly requested that the FDA provide Customs with "written national standards" for the interdiction of pharmaceuticals which do not meet the FDA's specifications for entry into the United States. In her response dated October 11, 2000, Dr. Henney indicated that the "Federal Food, Drug, and Cosmetic Act does not contain any exemption for products imported for personal use; it provides for the refusal of admission of violative pharmaceuticals, regardless of the identity of the importer". This language is interpreted to mean that FDA wants Customs to hold "all" parcels of pharmaceuticals for FDA review without regard to any criteria provided by the FDA to minimize the enormous volume of such importations.

The visit of our joint Customs/FDA task force to the foreign mail facility outside of Los Angeles during the week of October 23rd indicated that this policy is not practical due to present FDA staffing levels. We will discuss the experience of the task force in greater detail during our meeting currently scheduled for December 11th. However, since the present FDA policy still calls for zero tolerance, Customs is set to begin an initiative that will measure the impact that this policy will have on both Customs and the FDA if implemented fully.

Accordingly, for a two-day period commencing on December 4, 2000 and concluding on December 5, 2000, Customs will require all 14 foreign mail facilities and the courier hub located in Memphis to hold "all" parcels of pharmaceuticals for FDA review. These parcels will not be released until reviewed by the FDA and approval is granted. We hope, through this initiative, to compile specific figures on the magnitude of the importations and the percentages actually receiving FDA review under the present FDA policy.

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Depending on the outcome of this initiative, consideration for formal permanent implementation will be made. We hope to have some results for discussion prior to our December 11th meeting. If you would like further details on this initiative, please feel free to have a member of your staff contact Mr. Paul K. Schwartz at (202) 927-0667.

Sincerely,



Bonni G. Tischler
Assistant Commissioner
Office of Field Operations

CC: Commissioner
Assistant Commissioner, Congressional Affairs
Assistant Commissioner, OI
Executive Director, Field Operations



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

November 28, 2000

Bonni G. Tischler
Assistant Commissioner
Office of Field Operations
U.S. Customs Service
1300 Pennsylvania Avenue, N.W.
Washington, D.C. 20229

DEC - 5 2000

Dear Ms. Tischler:

This is in reference to your letter dated November 22, received via facsimile transmission on November 24, concerning your initiative to hold "all" parcels of pharmaceuticals received in the 14 foreign mail facilities and the courier hub located in Memphis beginning on December 4 and concluding on December 5.

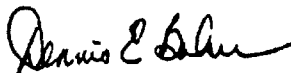
You indicate in your correspondence that this is being done based upon language contained in a letter sent to Customs Commissioner Raymond Kelly by FDA Commissioner Dr. Jane E. Henney on October 11, 2000, which you have interpreted to mean that FDA wants Customs to hold "all" parcels of pharmaceuticals for FDA review. This is to be done without regard to any criteria provided by the FDA to minimize the enormous volume of such importations. We suspect that you may have misinterpreted the intent of such language.

It was our understanding that Customs and FDA would work together to develop "written national standards," and that our joint Customs/FDA task force to the Carson mail facility would gather information which would assist in developing such standards. We had anticipated beginning discussion and development of possible standards, which could be used in conjunction with our "Personal Import Guidance" at our meeting scheduled for December 11. You are correct in your determination that a policy to hold all pharmaceuticals for FDA review is not practical based upon present FDA staffing levels, and we had hoped to discuss alternatives at the December 11 meeting. We are uncertain that your initiative scheduled for December 4-5, 2000, will contribute meaningful new information which can be used to resolve this problem. We are certain, however, that it could have an extremely disruptive effect on the movement of the mail and courier parcels.

We appreciate your desire to compile specific figures on the magnitude of the pharmaceutical importations that do not meet FDA's specifications for entry into the United States. This very short notice, however, leaves us with little time to plan for such an initiative which, I am advised, may require the dedication of more than 100 employees. Such a diversion of resources will have a tremendous impact on our ability to conduct other

activities. As I mentioned previously, we had hoped to have an opportunity to discuss this issue as well as the evaluation of the joint task force to the foreign mail facility outside of Los Angeles at the December 11 meeting. If this is agreeable, we would suggest that the December 4 and 5 initiative be postponed until we have time for further discussion and planning at our scheduled meeting on December 11 here in Rockville, MD.

Sincerely,



Dennis E. Baker
Associate Commissioner for
Regulatory Affairs

HEALTH:FDA:Drugs (internet sale of)

JDD/WJT:CK:crvh

ONE HUNDRED SEVENTH CONGRESS

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CHARLES F. BASS, NEW HAMPSHIRE	

DAVID V. MARIENTAN, STAFF DIRECTOR

U.S. House of Representatives
Committee on Energy and Commerce
 Room 2123, Rayburn House Office Building
 Washington, DC 20513-6113

March 8, 2001

Bernard A. Schwetz, D.V.M., Ph.D.
 Acting Principal Deputy Commissioner
 Food and Drug Administration
 5600 Fishers Lane
 Rockville, Maryland 20857

Dear Dr. Schwetz:

Staff members of the Committee on Energy and Commerce recently traveled to Carson City, California, to inquire into the pilot project initiated by the Food and Drug Administration (FDA) and the U.S. Customs Service (Customs) at their Los Angeles mail facility. That project was undertaken by both agencies to better assess both the quantity and types of pharmaceutical products increasingly being shipped into the U.S. from foreign sources. This undertaking was also intended to gather key data needed to assess what changes are necessary to the system currently in use by FDA and Customs to identify and process these shipments, and to assess the viability of the current system. Based on what has been reported to us, we believe that the present system utilized by both agencies requires significant retooling and additional resources.

FDA and Customs officials at the California facility reported that, on average, several hundred (perhaps as many as 700) packages containing pharmaceuticals were detained each day during the course of the pilot project. Although FDA provided more staff to the pilot project than is normally employed in this facility (meaning more illegal shipments should be detected), the number of foreign pharmaceuticals reportedly entering this facility is both sizeable and worrisome.

Of the packages detained and reviewed, a significant number reportedly showed no indication that a licensed doctor prescribed the drug. Moreover, many detained packages were mislabeled (or misbranded). For example, some were labeled as common over-the-counter products, yet in fact contained controlled substances. Finally, many of the detained packages contained drugs readily available here in the U.S. and, with even a liberal interpretation of FDA's personal use policy, would not be permitted to enter the U.S. under existing law.

Bernard A. Schwetz, D.V.M., Ph.D
Page 2

The Carson facility alone receives several thousand pharmaceutical shipments each week from foreign sources. These require analyses of pharmaceutical packages, determining whether to permit their entry under FDA's personal use policy, and completing all necessary data-entry and paperwork. FDA officials reported that with three full-time employees, they were only able to process approximately 30 packages a day. What happened to the remaining detained packages that could not be processed during the pilot project? More broadly, what happens in a "normal" week when significantly fewer FDA resources are dedicated to this facility? Do thousands of packages, even if initially detained by Customs, simply get delivered to the addressee without review?

If several thousand packages arrive each week at the Carson facility alone, and if FDA is generally able to assign only one person to process these packages (while that individual also handles other responsibilities), then the system is inadequate and incapable of protecting the public from potentially adulterated and unsafe medicines. Further, if one is able to extrapolate (even in part) the findings of this project to the numerous other mail facilities in the United States (examples such as Dallas, Texas; Oakland, California; Dulles, Virginia; and New York City), one can quickly grasp the potential magnitude of this problem. We urge your immediate attention to this state of affairs.

Given our concerns about this matter, which should come as no surprise to FDA, we would like you to provide us with the following:


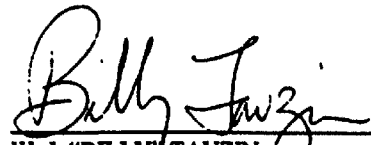
- (1) A detailed report describing the findings of the Carson mail facility pilot project, and any analysis by FDA and Customs to determine if these findings can be extrapolated to the nation's other mail facilities;
- (2) An analysis of the implications of the Carson project's principal findings as they relate to public health;
- (3) An inventory of both the types of drugs that were identified in this project and the countries from which those drugs came;
- (4) A detailed plan on how FDA and Customs intend to address this problem. As part of this plan, please describe how FDA will coordinate this plan with Customs and provide a detailed Memorandum of Understanding (MOU) between the two agencies on how you both expect this problem to be resolved. In addition to this MOU, please also include a detailed discussion of what resource shortfalls currently exist, as well as a description of what resources are needed to properly safeguard public health.
- (5) As many of the packages being stopped at the Carson mail facility appear to originate in New Zealand, please provide a description of what steps either agency has undertaken to work with that country to prevent the continuance of such

Bernard A. Schwetz, D.V.M., Ph.D
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shipments. (Note: It is not a sufficient response to indicate that the agency has sent "cyber-letters" to any potential offenders, inasmuch as many of these shipments appear connected to Internet pharmacies. Short of serving as a public relations device to signal that the agency is attempting to address this matter, we have seen little proof of this device's effectiveness in curbing illegal shipments of drug products into the U.S. from foreign sources.) Please provide only direct contacts made between U.S. governmental agencies and New Zealand authorities, and the nature of those contacts.

Please provide these responses by Friday, March 30, 2001. If you have any questions regarding this matter, you may contact us or have your staff contact either Chris Knauer, Minority Investigator, (202/226-3400) or Alan Slobodin, Oversight Counsel, (202/225-2927) of the Committee on Energy and Commerce.

Sincerely,


JOHN D. DINGELL
RANKING MEMBER
W. J. "BILLY" TAUZIN
CHAIRMAN

cc: The Honorable James C. Greenwood, Chairman
Subcommittee on Oversight and Investigations

The Honorable Peter Deutsch, Ranking Member
Subcommittee on Oversight and Investigations

HEALTH:FDA:Drugs (import presc. drugs from Mexico) 04:0+1 97 JUDICAID

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DAVID V. MARVENTANT, STAFF DIRECTOR

U.S. House of Representatives
Committee on Energy and Commerce
 Room 2123, Harbun House Office Building
 Washington, DC 20515-6113

March 14, 2001

Bernard Schwetz, D.V.M., Ph.D.
 Acting Principal Deputy Commissioner
 Food and Drug Administration
 Room 14-71 (HF-1)
 5600 Fishers Lane
 Rockville, Maryland 20857

Mr. Charles Winwood
 Acting Commissioner
 United States Customs Service
 1300 Pennsylvania Avenue, N.W.
 Washington, D.C. 20229

Mr. Donnie R. Marshall
 Administrator
 Drug Enforcement Administration
 Information Services Section (CPI)
 2401 Jefferson Davis Highway
 Alexandria, Virginia 22301

Dear Dr. Schwetz, Acting Commissioner Winwood, and Administrator Marshall:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce is examining implementation of policies concerning personal importation of prescription drugs at the Mexico-U.S. border. Last month, Committee staff traveled to San Ysidro, California, to meet with U.S. Customs Service and U.S. Food and Drug Administration (FDA) officials in order to discuss a range of issues relating to U.S. residents traveling to Mexico to purchase prescription drugs. Specifically, staff was interested in knowing (1) the sources and quality of the drugs being purchased at border pharmacies; (2) the types of drugs being declared at the Mexico-U.S. border; and (3) FDA and U.S. Customs' interpretations of current policies that allow for some drug importation for personal use.

Thousands of U.S. residents cross into Mexico each week; many use such excursions to purchase prescription drugs from the numerous conspicuous pharmacies that exist on the Mexican side of the border. According to the August 24, 2000, San Diego Weekly Reader, it is

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estimated that there are 1,000 pharmacies in Tijuana, Mexico, or one pharmacy for every 1,300 residents. By contrast, the city of San Diego has about 125 pharmacies, or one pharmacy for every 10,800 residents. According to the same article, of the Tijuana pharmacies that sell controlled drugs, "around 20 percent of them will sell without a prescription, and most of the rest will recommend a doctor who will give you the prescription."

During the visit to the Tijuana border at the port of San Ysidro, U.S. Customs Service inspectors discussed the problem of personal importations of prescription drugs and controlled substances such as OxyContin, a narcotic painkiller that reportedly has been a factor in the deaths of at least 120 people in the U.S. In echoing these concerns about personal importation of controlled substances, the Texas Commission on Alcohol and Drug Abuse in its December 2000 Research Brief entitled, "Substance Abuse Trends in Texas," stated: "A major problem [related to Texas drug abuse] is that Mexican pharmacies sell many controlled substances to U.S. citizens who declare these drugs and then legally bring up to a 90-day supply into the state."

In 1998, the Congress responded to concerns about U.S. residents bringing in controlled substances over the Mexican border into the U.S. by enacting an amendment to the Controlled Substances Import and Export Act. That amendment limited personal imports of controlled substances at land ports of entry to 50 dosage units for U.S. residents who did not possess a valid U.S. prescription. Nevertheless, both the enactment and the interpretation of that law appear to have unintentionally exacerbated the problem of persons bringing potentially dangerous substances into the United States.

Currently, some internal policies at the U.S. Customs Service appear almost "geared" toward permitting U.S. residents to personally import amounts of 50 dosage units or less of controlled substances. A June 29, 2000, internal memorandum by the U.S. Customs Service Port Director of Laredo, Texas states:

"In summary, the controlled substances must be declared to Customs upon arrival, be for that individual's personal use, and be in their original container. If all these conditions are met, a United States resident may import the type and amount of the controlled substance (except those in Schedule I or other prohibited substances) as specified on the prescription. If the controlled substances are declared, but the United States resident does not possess a valid prescription issued by a practitioner as defined above, the United States resident may bring in only an amount not to exceed 50 dosage units. Remember that the 50 dosage units amount applies to each type of controlled substance being imported. In other words, if the resident is importing 3 different types of controlled substances, the resident may import up to 50 dosage units for each type for a total of 150 dosage units."

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What this memorandum and other policies do not emphasize, at least not explicitly, is that (1) importing such drugs may violate other Federal and state laws, and (2) that Customs inspectors have the enforcement discretion to refuse their admission, particularly in cases where potentially dangerous drugs are involved. (One could argue, for example, that any foreign-made controlled substances brought into this country by a U.S. resident traveler by definition would violate the Federal Food, Drug, and Cosmetic Act because these products are automatically, under the law, deemed adulterated, misbranded, or unapproved drugs.) This memorandum alone seems to suggest that the general rule at the border for Customs officials to follow is to allow individuals to bring in such drugs, while the exception is to deny their entry.

Finally, while some policies do attempt to provide field staff with more balanced guidance in this regard, the advice given is often unrealistic. For example, a December 15, 1999, U.S. Customs Service Headquarters Directive, 3310-006, notes that personal amounts of 50 dosage units or less may be precluded from import based on all other applicable Federal and state laws. That Directive states:

"When the type of drug, the quantity, or the combination of various drugs arouse suspicions, U.S. Customs Inspectors should contact the nearest FDA office (or DEA [Drug Enforcement Administration] office if controlled substances are involved) for advice. These offices will provide guidance concerning whether to release or detain the article."

The obtaining of such guidance is simply impractical. Committee staff visits to the ports of Laredo, Texas, and San Ysidro, California, (two of the world's largest border crossings) confirmed that constrained resources do not allow for either FDA or DEA personnel to have even a single person physically located at these checkpoints (during all hours of operation) for such consultations. The notion that Customs inspectors could somehow detain U.S. residents during the crush of tourist traffic at border crossings while trying to contact FDA or DEA personnel on the telephone for advice is simply unrealistic. In fact, existing Customs inspectors, in some cases, are valiantly trying themselves to make determinations of suspicious imports by consulting manuals or other online information sources on various prescription drugs. In short, we believe that these inspectors need clearer guidance than the current 50 dosage-unit policy and stronger support for precluding suspicious personal imports of controlled substances.

We understand that the DEA, U.S. Customs Service, and the FDA will be meeting the week of March 12, 2001, with the Committee staff to present a unified recommendation on how to improve policies in the handling of controlled substances brought across the border. Please treat this letter as authorization to provide the Committee staff, to the extent appropriate, any non-public information during this briefing.

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In addition, please provide the following by Friday, March 30, 2001:


1. Because a requirement exists that any drugs brought into the U.S. through a land border must be declared, please provide all formal or informal lists of all controlled substances known to be imported by U.S. residents at the Mexico-U.S. border since March 13, 2000. If no lists exist, please explain why that is the case.
2. All records relating to communications since March 13, 2000, (including those between the FDA, the DEA, or the U.S. Customs Service) concerning the abuse potential of controlled substances listed above.
3. All records relating to communications since March 13, 2000, (including those between the FDA, the DEA, or the U.S. Customs Service) raising concerns about controlled substances imported by U.S. residents at the Mexico-U.S. border.
4. All records relating to communications since March 13, 2000, (including those between the FDA, the DEA, or the U.S. Customs Service) concerning advice on personal imports of controlled substances.
5. All records since March 13, 2000, relating to a tracking system of declared personal import drug entries.


Please note that, for the purpose of responding to these requests, the terms "records" and "relating" should be interpreted in accordance with the attachment to this letter.

Thank you for your assistance. If you have any questions, please contact us or have your staff contact Alan Slobodin of the Majority Committee Staff at (202) 225-2927 or Christopher Knauer of the Minority Committee staff at (202) 226-3400.

Sincerely,


W.J. "BILLY" TAUZIN
CHAIRMAN


JOHN D. DINGELL
RANKING MEMBER


JAMES C. GREENWOOD
CHAIRMAN
SUBCOMMITTEE ON OVERSIGHT
AND INVESTIGATIONS


PETER DEUTSCH
RANKING MEMBER
SUBCOMMITTEE ON OVERSIGHT
AND INVESTIGATIONS

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.
2. The terms "relating," "relate," or "regarding" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.

FLM:INTERNET (selling drugs online)
HEALTH:FDA:Drugs--(same as above)

Cy: 2+5

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**U.S. House of Representatives
Committee on Commerce**

Room 2125, Rayburn House Office Building
Washington, DC 20515-6115

February 28, 2000

The Honorable Raymond Kelly
Commissioner
United States Customs Service
1300 Pennsylvania Avenue, N.W.
Washington, D.C. 20229

Dear Commissioner Kelly:

We appreciate your providing Committee staff with the opportunity to visit the U.S. Customs' mail inspection facility at Dulles International Airport in connection with our investigation into the shipment into the United States of pharmaceuticals purchased over the Internet. As your agency clearly recognizes, these Internet sites have multiplied dramatically over the past year. As these activities will likely increase in the near future, demands on existing governmental resources, including your agency, will only increase.

According to your inspectors, illegal pharmaceuticals make up the bulk of illegal contraband detained for cause at the Dulles facility. Many of these originate from online pharmacy transactions. We also understand that most of these name-brand products detained cannot be verified as authentic, or even as products made in accordance with U.S. Food and Drug Administration standards. Further, we understand that of those pharmaceuticals detained, a significant amount arrive with no information (such as dosage instructions, warnings of potential drug interactions, side effects, etc.) or even proof that a licensed physician or pharmacist was involved in the transaction. In fact, inspectors report that many of the pharmaceuticals simply arrive in plastic ziplock bags with nothing indicating the bags' contents. Such practices place the public at considerable risk, and are clearly inconsistent with the various U.S. laws and regulations designed to protect consumers from dangerous or ineffective drugs.

As you may know, we have been investigating a number of issues relating to this problem over the past year-and-a-half, including what actions the Federal Government is taking or should take, and what resources, including both personnel and technologies, are required to do the job. We understand that some agents and inspectors already feel overwhelmed by this problem. Consequently, we would appreciate your assistance in providing us with the following information:

The Honorable Raymond Kelly
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- (1) What resources does your agency currently dedicate to stopping the shipment of illegal pharmaceuticals into the U.S. by Internet pharmacies, and by what means? How significant does your agency estimate this problem to be (by volume seized, for example)? What future resource needs do you estimate your agency will need to address this matter? Finally, if any additional resources are needed, please indicate specifically how they would be used.
- (2) Please provide us with a brief description of the types of pharmaceutical products now being seized by inspectors at the Dulles mail facility. For example, of the packages detained, please provide: (a) the types of pharmaceutical products being found; (b) the frequency and quantity at which you are finding them; and, (c) the brand name and manufacturer (if known) of the major products.
- (3) If your agency has determined or suspects that any of the products identified in your response to question number 2 are counterfeit, please provide the basis for your determination or suspicion. If your agency has discovered counterfeit pharmaceuticals, please indicate if routine, from where such products are being sent.
- (4) Generally, of the pharmaceutical products detained by your agency, please indicate, if possible, the percentage of such products that are being shipped into the U.S. via an Internet pharmacy transaction.

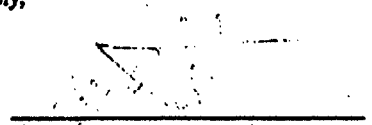
Finally, we are interested in arranging an additional visit to the Dulles mail facility for members of the Oversight and Investigations Subcommittee. We would appreciate your assistance in arranging such a visit at a mutually agreeable date within the next several weeks.

We appreciate the effort by your agency on this important public health matter, and continue to look forward to working with you in the future. Your timely attention to this response is also appreciated. If you have any questions about this matter, please feel free to contact us directly or have your staff contact Mr. Christopher Knauer of the Commerce Committee Democratic staff at (202) 226-3400.

Sincerely,



JOHN D. DINGELL
RANKING MEMBER
COMMITTEE ON COMMERCE



RON KLINK
RANKING MEMBER
SUBCOMMITTEE ON OVERSIGHT
AND INVESTIGATIONS

The Honorable Raymond Kelly
Page 3

cc: The Honorable Tom Bliley, Chairman
Committee on Commerce

The Honorable Fred Upton, Chairman
Subcommittee on Oversight and Investigations

The Honorable Michael Bilirakis, Chairman
Subcommittee on Health and the Environment

The Honorable Sherrod Brown, Ranking Member
Subcommittee on Health and the Environment

The Honorable Jane E. Henney, M.D., Commissioner
Food and Drug Administration

MARVIN D. SHEPHERD
College of Pharmacy
University of Texas at Austin
Austin, Texas 78712

CLINICAL THERAPEUTICS/VOL. 18, NO. 6, 1996

Pharmaceutical Products Declared by US Residents on Returning to the United States from Mexico

E. Kristin McKeithan, MS, and Marvin D. Shepherd, PhD
College of Pharmacy, University of Texas at Austin, Austin, Texas

ABSTRACT

The overall objective of this research project was to measure the types and amounts of Mexican drug products being purchased and declared to US Customs by US residents crossing the border in Laredo, Texas. Data for this study were obtained from the US Customs Declaration Form, which each person completes as he or she reenters the United States. Data included demographic information as well as the types and quantities of medications purchased. Data were collected from a randomly selected sample of 84 days between July 1994 and June 1995. A total of 5624 declaration forms were analyzed. The average age of people who declared medications was 34.5 years. Only 9.3% of the people were 50 years of age or older. Fourteen of the top 15 drug products declared are classified in the United States as "controlled" substances. In ex-

amining the quantities of medications being declared, on average 11,057 diazepam tablets were declared each day, which is equivalent to 4,035,842 diazepam tablets per year. On average 4033 tablets of flunitrazepam were declared each day, which is equivalent to 1,472,045 tablets a year declared at one US port of entry. On average, there were 2.48 drug products listed on each declaration form. The majority of the drug products were controlled substances and, based on the types and quantities of products being declared, many questions can be raised with regard to US policies on the control and safety of Mexican drugs coming into the United States.

INTRODUCTION

The extent to which US residents cross the border into Mexico to purchase pharmaceutical products has been widely publicized in the lay and academic press.¹⁻³

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E.K. McKEITHAN AND M.D. SHEPHERD

One study has reported that 25% of the US residents who enter Mexico as tourists purchase pharmaceutical products.⁴ Pharmacy owners and managers who operate pharmacies along the Texas-Mexico border have estimated that 25% of their patient clientele visit Mexican pharmacies for medications.⁵ A study conducted by Familles USA reported that 32% of the US residents living along the US side of the border visited a Mexican pharmacy in the previous year.⁶ In addition, a 1992 study reported that 81% of the patients who visited a Texas health care clinic in El Paso traveled to Juarez, Mexico, to purchase medications. A total of 55% of these people reported that they purchase medications in Mexico several times a year, with 69% indicating that they had purchased pharmaceutical products in Mexico within the last month.⁷

The reported main reasons why US residents travel to Mexico to purchase pharmaceutical products are lower drug prices when compared with the US pharmaceutical market and easier access to prescription drug products.⁸ The lower drug costs and easy access make Mexican medications very attractive to US residents who have chronic diseases that require expensive medications. Thus the elderly, retirees who are living on fixed incomes, and others who are interested in saving money see the lower-priced Mexican drugs as a relief from the expensive US health care system.^{8,9}

The single most common reason US residents visit Mexico to acquire pharmaceutical products is the low prices of Mexican medications. Mexico's National Health Care System controls the price of pharmaceuticals. Retail pharmacies can lower their selling price as much as 20% below the government ceiling price but cannot raise their price above the ceiling

price. In the marketplace, it is not uncommon for customers to haggle with pharmacists or pharmacy employees about the price of medications.

The second major reason US residents visit Mexico to purchase prescription medication is the easy access. Major differences exist between the United States and Mexico in how drug products are regulated and distributed. Many of the products referred to as "legend" drug products in the United States—those products that require a prescription—are readily available as over-the-counter drug products in Mexico and require no prescription. Pharmaceutical products that have the potential for abuse or are dangerous to use and need supervision from a health care practitioner require a prescription. These products are primarily narcotics and psychotropic medications. Prescriptions in Mexico can be written by physicians, dentists, homeopathic physicians, veterinarians, health professionals in the social services, nurses, and midwives.⁹ Although a prescription is required by law, it is not uncommon to obtain pharmaceutical products from retail pharmacies in Mexico without a prescription.^{7,9} Furthermore, obtaining a prescription for these regulated products is not difficult in Mexico.¹⁰

The literature is weak in documenting the types and amounts of pharmaceutical products US residents purchase in Mexico. Most studies have concentrated on the activity of US residents living along the US-Mexico border. However, it is unknown to what extent nonborder US residents patronize Mexican pharmacies. After spending an afternoon with US Customs officials in Laredo, Texas, and visiting pharmacies in Nuevo Laredo, Mexico, we realized that quantities of Mexican drug products being brought

from Mexico into the United States were greater than anticipated. We also realized that the situation did not just apply to the Texas border area. US residents from many states were crossing the border in Laredo and returning to the United States with a variety of drug products in large quantities.

The overall objective of this research project was to document the types and amounts of Mexican drug products that were declared by US residents at the US Customs border crossing in Laredo, Texas. Other objectives for this project were to determine the demographic profile of US residents who have declared pharmaceutical products and to determine the number of people declaring such products who are from Texas and from other states.

SUBJECTS AND METHODS

The data used in this study were collected from the US Customs Declaration Form 6059B(013194) at the Laredo US Customs border crossing, Bridge One. Bridge One handles visitor travel by foot and automobile but not commercial travel such as large trucks or tractor trailer vehicles. The procedure for reentering the United States through Customs consists of Customs officials questioning visitors to Mexico about their citizenship status and randomly inquiring about any purchases made in Mexico. If one of the purchases includes medications, the tourists are instructed to complete a declaration form. The declaration forms are signed, dated, and turned over to Customs officials. Customs agents visually inspect all medications purchased to make sure the form was completed accurately.

Declaration information was collected over a randomly selected number of days

for 12 months. One Monday, Tuesday, Wednesday, Thursday, Friday, Saturday, and Sunday for each month between July 1994 and June 1995 was randomly selected, resulting in a sample of 84 days. The reason for this method of selecting days was to control for any effects of seasonality, day of the week, or time of the month.

The variables collected from the US Customs Declaration Form included date of the claim, state of residence, country of citizenship and residence, value of each product purchased and total value of all goods purchased in Mexico, names of drugs, and the number of packages purchased. The person's sex was inferred from his or her name. The day of the week was translated from the date of the claim. Names of the individuals who completed the declaration forms were not collected and thus were not included in the database. In addition, names of the Customs officials who supervised the declaration process were not included in the database.

Many of the pharmaceutical products purchased in Mexico have different names than those used in the United States, and many products are not available in the United States. Mexico's version of the *Physicians' Desk Reference*®, *Diccionario de Especialidades Farmaceuticas*, was used to identify drug products and determine drug therapeutic categories.¹¹ Mexican pharmaceutical products are packaged and sold in preset quantities per package per container. This same reference book contains information on product packaging and was used to determine the number of tablets, capsules, or ampules per package of the drug listed on the declaration form. In most instances, drug strengths were not listed on the declaration forms; thus all products of the same

E.K. McKEITHAN AND M.D. SHEPHERD

name were grouped together regardless of the dose strength.

RESULTS

Demographic Description of Sample

During the 84 days sampled, a total of 5624 declaration forms were submitted. Men completed 3391 (60.3%) forms, and women completed 2178 (38.7%) forms. The sex of the person declaring the pharmaceutical products could not be identified for 55 (1.0%) forms. The average age of people who declared medications was 34.5 ± 10.7 years. On average, the men were younger than the women (33.2 years vs 34.8 years). The median age was 33 years for men and 35 years for women. People older than 50 years only represented 9.3% of the sample. People younger than 40 years represented more than 50% of the people declaring drug products. Overall, an average of 67 people declared pharmaceutical products per day.

Geographic Distribution of People

A total of 39 states were listed as the state of residence on the declaration form. People who resided in Texas accounted for 63.9% ($n = 3595$) of the total. Louisiana and Oklahoma ranked second and third highest in the number of people declaring drug products. A total of 15.4% ($n = 867$) of the people were from Louisiana and 8.0% ($n = 453$) were from Oklahoma. People declaring medications came from as far away as Alaska, Washington, Minnesota, Massachusetts, and Florida. All geographic regions of the country were represented, nearly 40% of the people making declarations were not residents of Texas.

Types and Quantities of Pharmaceutical Products Declared

The 5624 declaration forms contained 13,939 drug product entries. These entries represented 112 different drug products in 36 therapeutic classes. The average number of drug products declared per day was 166.2. Extrapolating to a full year, we estimated that 60,663 drug products were declared at the Laredo border crossing by 24,455 people during the study's 12-month time frame (166.2 drug product entries per day \times 365 days, and 67 people per day \times 365 days). An average of 2.48 drug products were listed on each declaration form.

The top 15 drug products, by number of people declaring the product and the total units declared, are listed in Table I. These top 15 drug products represent 94.1% ($n = 13,142$) of all drugs listed on the declaration forms. Diazepam (Valium®, Productos Roche, S.A. de C.V., Benito Juarez, Mexico), the drug listed most frequently on the declaration forms, was declared by 69.8% ($n = 3923$) of the people making drug declarations. The average number of diazepam tablets declared was 236.8 tablets per person. Diazepam was followed by another benzodiazepine product, flunitrazepam (Rohypnol®, Productos Roche, S.A. de C.V., Benito Juarez, Mexico). Flunitrazepam was brought into the United States by 42.5% ($n = 2393$) of the people. The average number of tablets declared per person was 141.6. Third on the list was an anxiolytic product, alprazolam (Tafil®, Upjohn, S.A. de C.V., Coyoacan, Mexico), with 23.4% ($n = 1316$) of the people declaring this product. Fourth on the list was a stimulant product used for weight reduction called diethylpropion (Femmate Dospan®, Laboratorios Legem de Mexico).

Table I. Top 15 pharmaceutical products ranked by number of people declaring the product and total quantity declared.

Rank and Drug Product (therapeutic class)	Mexican Brand Name	Total No. of People ^b (% of all declarations)	Total No. of Units (tablets, capsules)
1. Diazepam (benzodiazepine)	Valium® (Productos Roche, S.A. de C.V., Sanito Juarez, Mexico)	3923 (69.8%)	928,800
2. Flunitrazepam (benzodiazepine)	Rohypnol® (Productos Roche, S.A. de C.V.)	2393 (42.5%)	336,760
3. Alprazolam (benzodiazepine)	Talzi® (Upjohn, S.A. de C.V., Sanito Juarez, Mexico)	1316 (23.4%)	284,130
4. Dihydroxyphenyl (stimulant)	Tamara Despar® (Laboratorios Laporte de Mexico, S.A. de C.V., Merida, Mexico)	1013 (18.0%)	111,860
5. Oxycodone (narcotic analgesic)	Nasporcides® (Rhône-Poulenc Rorer, S.A. de C.V., Sanito Juarez, Mexico)	862 (15.3%)	42,530
6. Phenazone (stimulant)	Diminex® (Pisar de Mexico, S.A. de C.V., Mexico City, Mexico)	849 (15.1%)	79,140
7. Clonazepam (stimulant)	Azanil® (Grupo Roussel, S.A. de C.V., Coyocacan, Mexico)	596 (10.6%)	92,760
8. Codeine/APAP (narcotic analgesic)	Tylen® (Cilag de Mexico, S.A. de C.V., Coyocacan, Mexico)	503 (8.9%)	16,230
9. Propoxyphene (narcotic analgesic)	Darvon® (Eli Lilly y Compania de Mexico, S.A. de C.V., Coyocacan, Mexico)	467 (8.3%)	37,940
10. Morphine (injectable narcotic analgesic)	Nubain® (Rhône-Poulenc Rorer)	362 (6.4%)	1,810
11. Diazepam/APAP/propoxyphene (benzodiazepine)	Qual® (Laboratorios Silanes, S.A. de C.V., Sanito Juarez, Mexico)	227 (4.0%)	13,800
12. Triazolam (benzodiazepine)	Halcion® (Upjohn, S.A. de C.V.)	217 (3.9%)	16,470
13. Methylphenidate (stimulant)	Ritalin® (Ciba-Geigy Mexicana, S.A. de C.V., Coyocacan, Mexico)	159 (2.8%)	13,380
14. Lorazepam (benzodiazepine)	Ativan® (Wyeth, S.A. de C.V., Mexico City, Mexico)	145 (2.6%)	15,000
15. Carisoprodol/meprobamate (muscle relaxant)	Somaject® (Carter Wallace, S.A. Miguel Alemán, Mexico)	110 (2.0%)	10,890

APAP = acetaminophen.

S = Sustained Release Tablets.

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S.A. de C.V., Morelos, Mexico), and the fifth product was oxycodone (Neopercodan[®], Rhône-Poulenc Rorer, Benito Juárez, Mexico), a narcotic analgesic.

In looking at the remaining 10 products, one sees a similar trend in therapeutic categories. All products were narcotic analgesics, stimulants, or benzodiazepines, with the exception of one muscle relaxant. All of the top 15 products, which are available in the United States, are classified as "controlled substances" in this country. The products in the top 15 not available in the United States are flunitrazepam, clobenorex (Assalix[®], Grupo Roussel, S.A. de C.V., Coyoacán, Mexico), diazepam/acetaminophen/propoxyphene combination (Ques[®], Laboratorios Silanes, S.A. de C.V., Benito Juárez, Mexico), and cariso-

prodol/naproxen (Somalgic[®], Carter Wallace, S.A., Miguel Hidalgo, Mexico).

In just the 84 days sampled, close to 1 million tablets of diazepam were declared. On average, 11,057 tablets were declared per day. This is equivalent to 4,035,842 diazepam tablets declared and brought into the United States each year at one port of entry. For flunitrazepam, an average of 4033 tablets were declared per day, which is equivalent to approximately 1,472,045 tablets per year that were declared and brought into the United States through Laredo during the study period. In addition, 1,234,613 tablets of alprazolam were declared.

Because different products are supplied in different quantities per package, an analysis by number of drug packages or

Table II. Top 15 pharmaceutical products and total number of drug packages declared, mean number of packages per person, range in the number of packages declared per person, and package size.

Rank and Drug Product	Total No. of Packages	Mean No. of Packages per Person*	Range in No. of Packages per Person	No. of Units per Package
1. Diazepam	10,320	2.5	1-25	90
2. Flunitrazepam	11,292	4.6	1-18	30
3. Alprazolam	3157	2.4	1-16	90
4. Diethylpropion	3702	3.6	1-23	30
5. Oxycodone	4255	4.9	1-29	10
6. Phenemine	2638	3.4	1-20	30
7. Clobenorex	1546	2.6	1-15	60
8. Codeine/APAP	1623	3.2	1-12	10
9. Propoxyphene	1546	2.6	1-15	60
10. Nalbuphine	1447	4.0	1-15	5
11. Diazepam/APAP/propoxyphene	690	3.0	1-10	20
12. Triazolam	549	2.5	1-10	30
13. Methylphenidate	446	2.8	1-6	30
14. Lorazepam	374	2.6	1-12	40
15. Carisoprodol/naproxen	363	3.3	1-17	30

APAP = acetaminophen.

*Mean number of packages per person = total number of drug packages ÷ number of people declaring the drug.

containers was conducted (Table II). The most striking observations in Table II are the average number of packages per person and the range in number of packages declared. For example, the average number of drug packages declared per person for diazepam was 2.5, but at least one person declared 25 packages of diazepam. In other words, the person who declared 25 packages brought 2250 tablets of diazepam into the United States. Another person declared 18 packages of flunitrazepam, which contained 540 tablets.

DISCUSSION

The results of this research show a vast difference in the pharmaceutical product mix purchased and declared by US residents than was expected or even reported by the lay press or academic literature. The press has pointed out that many elderly and others who cannot afford US drug products frequently travel to Mexico to purchase medications for their ailments. However, the demographic profile of people declaring drugs at Bridge One in Laredo does not fit the description of the elderly, and the top 15 drug products do not fit the scenario of drugs for disease conditions commonly found in the elderly, such as hypertension, cardiovascular disease, or diabetes.

The results of this exploratory study show that a large quantity of controlled substances are coming across the border into the United States from Mexico. Some of these products may be for a legitimate use, such as the treatment and care of a disease condition. However, the types and quantities of products coming through US Customs raise some serious questions about this assumption. For example, nearly 70% of the people declaring drugs

declared diazepam, a benzodiazepine drug product, and more than 42% declared flunitrazepam, a product involved in a growing and serious problem of abuse in the United States. The legitimate use for flunitrazepam in Mexico is to treat severe insomnia, and it is used as a preanesthetic medication. Furthermore, the median ages for people declaring diazepam and flunitrazepam were 24 and 26 years, respectively. The researchers question the legitimate needs of hundreds of 20 year olds for diazepam and flunitrazepam. In addition, 1858 (33.0%) of the people in the data set declared at least one package of diazepam together with at least one package of flunitrazepam. The next section describing flunitrazepam explains the dangers of taking these two products in combination.

Flunitrazepam is gaining in popularity as a drug of abuse in the United States.¹² The lay press has reported that flunitrazepam is becoming the "culture" drug of the 1990s. It is a popular street drug, and sells for as much as \$5.00 a tablet in some regions.¹³ The street names for flunitrazepam are "roofies," "rope," "ropies," "roach," "the forget pill," "Mexican Valium," "roopies," "roach-2," "R-2" and "ruffies." It can be purchased in Mexico for about \$0.50 a tablet. It causes a "drunken stupor" and has been reported "to have more intoxicating power than a six-pack of beer."¹⁴ It has been estimated to be 10 times stronger than diazepam.¹² Furthermore, it has been reported to cause complete short-term amnesia, thus the name "the forget pill." It is extremely dangerous when mixed with alcohol and has been implicated in date rape cases.¹⁵

Flunitrazepam abuse has drawn so much attention that on March 5, 1996, the US Treasury Department decided to ban

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US residents from bringing flunitrazepam into the United States.¹⁶ Furthermore, on October 13, 1996, President Clinton signed legislation that makes it a crime to use a drug product as a weapon and adds 30 years to the sentence for rapists who subdue victims with "date rape drugs." This bill was a direct reaction to the increased abuse of flunitrazepam.

US Customs' requirements for bringing medications into the United States are that only a "reasonable" amount of medication can enter the United States, and that the medications are for personal use. US Customs port in Laredo has defined a "reasonable" amount of medication as a 90-day supply. However, each US Customs port of entry defines "reasonable" amount differently. All medicinal agents must be properly identified, and the person must have either a prescription or written statement from a physician stating that the medicines are being used under a physician's directions and are necessary for physical well-being.¹⁷

Furthermore, although US Customs allows the person to bring Mexican pharmaceuticals into the United States, the person may still be in violation of state and federal rules and regulations for prescription and controlled drug products. For example, in Texas, US residents returning from Mexico with controlled substances are in violation of the Texas and federal controlled substance regulations, because Mexican prescriptions for controlled substances are not valid in Texas unless the prescriber is licensed in Texas and is registered with the US Drug Enforcement Administration (DEA). Currently, there are no physicians in Mexico with a DEA registration. Second, the vast majority of drug products from Mexico are not properly labeled; thus they do not

conform with the Controlled Substance Act of 1970. Few medicinal products from Mexico have patient-specific drug labels. Finally, the drug product is in violation of federal law, because currently none of the products coming from Mexico are approved by the US Food and Drug Administration. Thus persons carrying controlled substances from Mexico are in possession of an illegal controlled substance and are subject to arrest.

Limitations

The prime limitation of this research was that the results of this study cannot be extrapolated to other border crossings in Texas or along the southwest border of the United States. No other ports of entry along the Texas-Mexico border use the declaration form for medications purchased in Mexico. Another limitation is the likely underestimation of the quantities of drug products being purchased in Mexico. This study concentrated on drug products that were declared. The drug quantities measured were purchased in Mexico, but the declarations do not represent purchases made by people who did not complete declaration forms or people who smuggled drug products into the United States. Medications seized by US Customs were also not included in this study. US Customs officials seize all medication if the quantity declared is not reasonable, the product is banned in the United States, or the person is discovered trying to smuggle drugs into the United States without making a declaration.

CONCLUSIONS

When work on this project began, we believed that the most frequent drug prod-

acts declared would be antibiotics and drugs for the treatment of chronic health conditions such as cardiovascular problems, arthritis, diabetes, and lipid management problems. However, this assumption was not supported by the research. The results of this study do not refute the possibility that many US residents travel to Mexico to purchase medications for the treatment of chronic health conditions. The results did show, however, that if people frequently travel to Mexico to obtain their chronic medications, they certainly are not declaring these products at the US Customs office in Laredo on their return to this country. A different research methodology and approach are needed to document the extent to which people are purchasing chronic medications in Mexico and returning to the United States through Laredo. Perhaps conducting this research project at a different US port of entry would have produced different results.

Even though the results were much different from what was anticipated, the findings do not diminish the importance of this study. The study's results highlight perhaps a much larger US health, social, economic, and policy problem than the one originally hypothesized.

ACKNOWLEDGMENTS

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UNITED STATES CUSTOMS SERVICE

Operation Safeguard

***A "snapshot" evaluation of pharmaceuticals
being imported into the U.S.***



**U.S. Customs Service
Laboratories & Scientific Services
Washington, D.C.**



UNITED STATES CUSTOMS SERVICE

Operation Safeguard



Objective of Operation "Safeguard":

- Ensure that pharmaceuticals imported into the U.S. are safe and genuine
- Given the explosion of Internet commerce, evaluate the scope and quantity of pharmaceuticals being imported into the U.S.

Issues:

- **Health & Safety Concerns:** Drugs may not contain an active ingredient, may be subpotent or overpotent, or may contain an improper ingredient which could interact with active substance rendering it inactive or toxic
- **Copyright & Trademark Violations**



UNITED STATES CUSTOMS SERVICE

Dulles & Oakland IMB's



Initial Findings

- **Approximately 100 international parcels per day contain pharmaceuticals**
- **None of the pharmaceuticals examined were reimportations of U.S. manufactured drugs**
- **A very small fraction of the packages are originating from Canada & Mexico**



UNITED STATES CUSTOMS SERVICE

What are we seeing....

- **Expired Product**
- **Pharmaceuticals in plastic bags with no labels, warning information or directions for use**
- **FDA unapproved product**
- **Product manufactured in third-world countries whose manufacturing facilities have not been inspected by the FDA**
- **Parallel Import "Gray Market" product whose formulations have not been approved by the FDA**
- **Commercial Shipments**

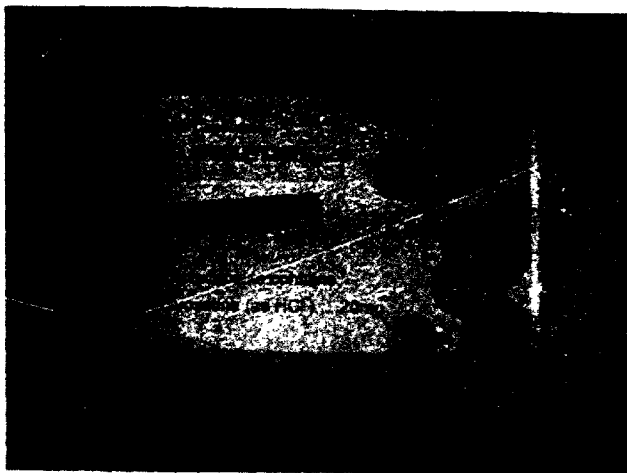


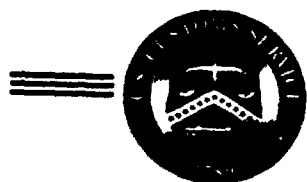


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Examples....

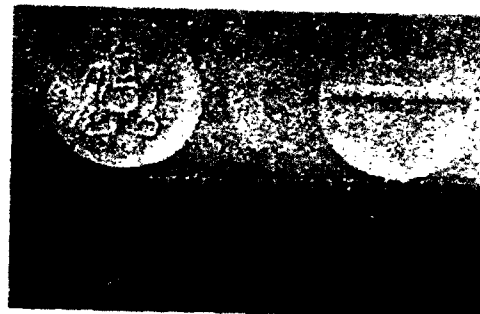
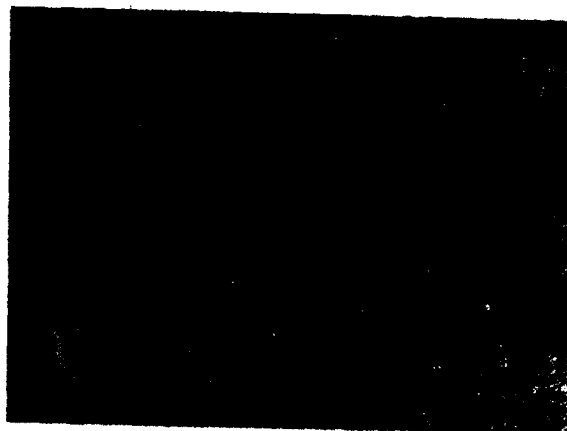
- **Fluoxetine (Prozac) manufactured in Iran with an expiration date of 2-81**





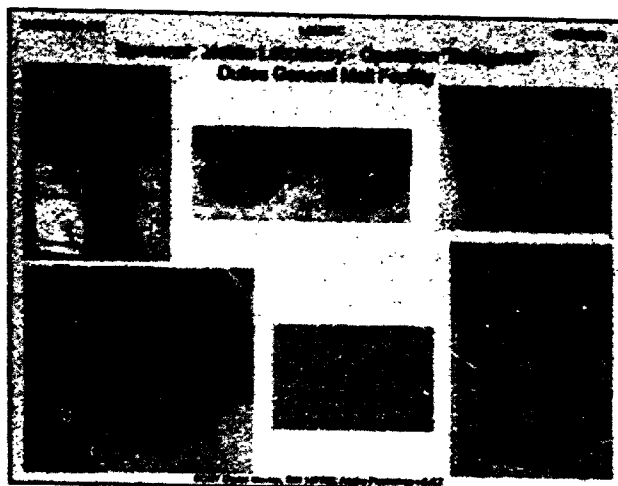
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- Ecstasy (MDMA) tablets concealed in pharmaceutical blister pack



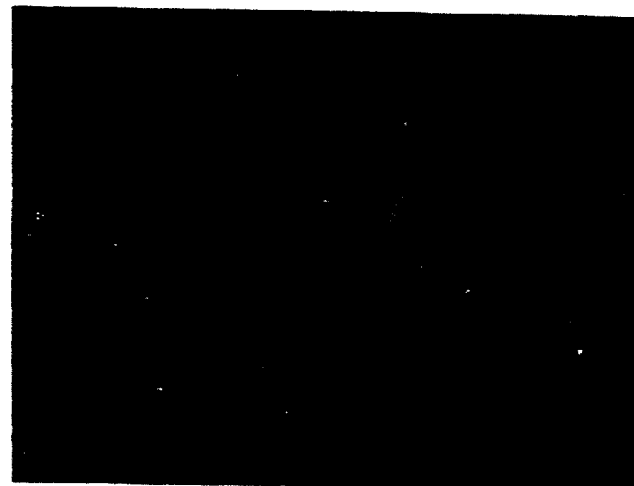


UNITED STATES CUSTOMS SERVICE



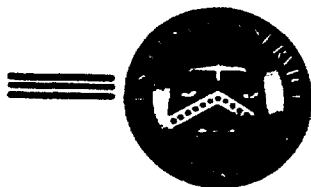
**Nootropil "smart drug"
imported from Thailand**

NOT APPROVED BY FDA



**Celebrex imported from
Ecuador**

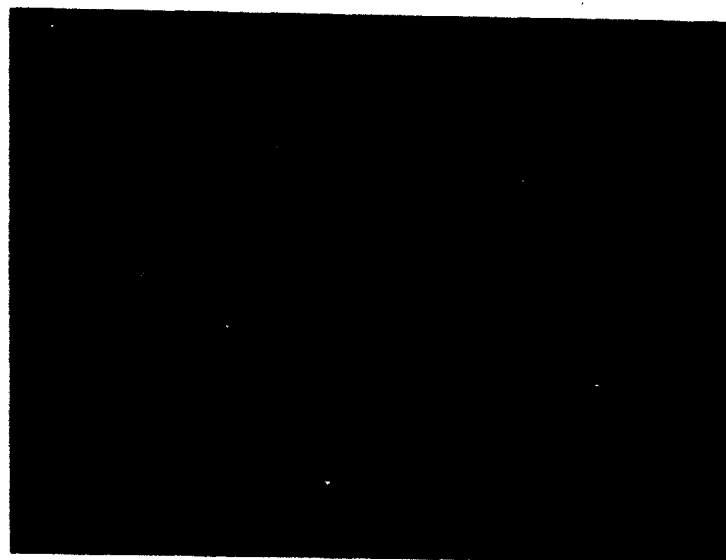
GRAY-MARKET PRODUCT



UNITED STATES CUSTOMS SERVICE



- Undeclared package containing 100 capsules of ribavirin



- 7 additional packages addressed to the SAME person



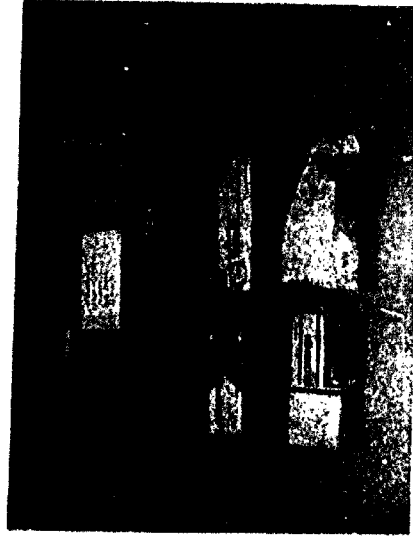
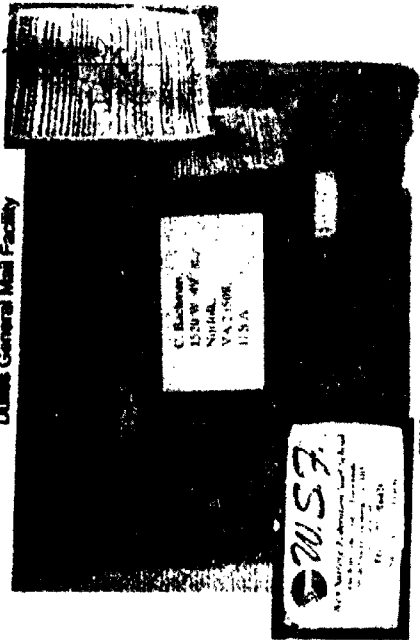
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ENCLOSURE

LEUAC

Savannah Mobile Laboratory - Operation "Seaguard"
Dulles General Mail Facility

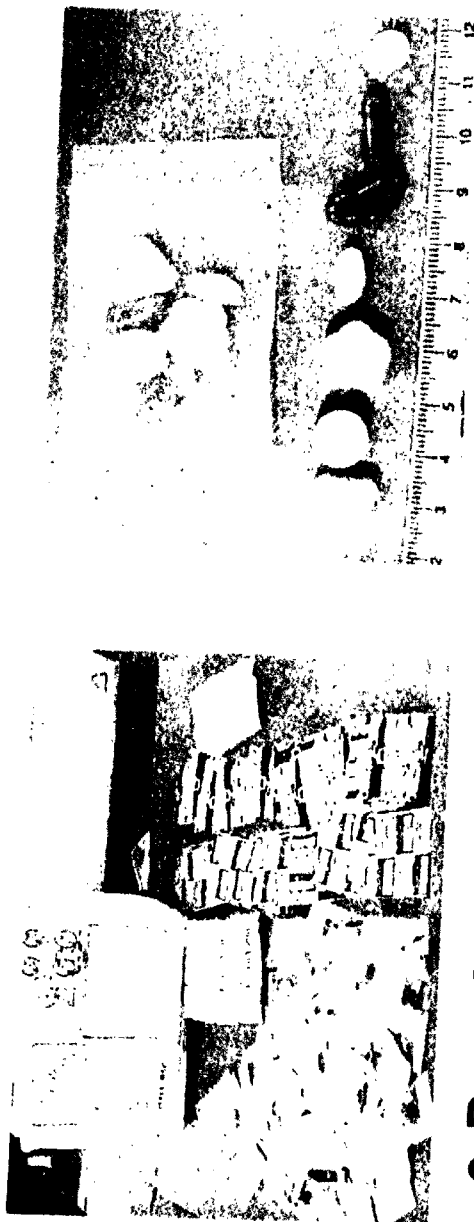
TO: 10/20/98



- Over 90 percent of the parcels examined have either false or no declarations



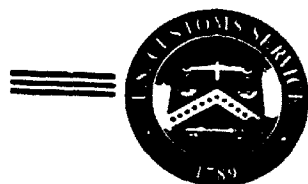
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- **Parcels with multiple pharmaceuticals**

Public Health Concerns...

- * **Adverse drug interactions**
- * **Allergic reactions**
- * **No medical supervision**

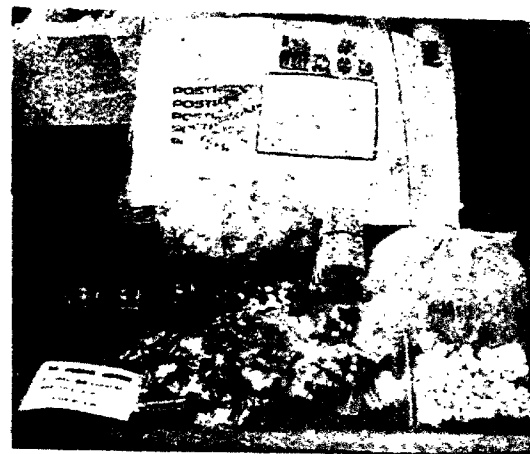


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- ***Commercial Quantities***



Parcel containing 24,060 pills of diclofenac



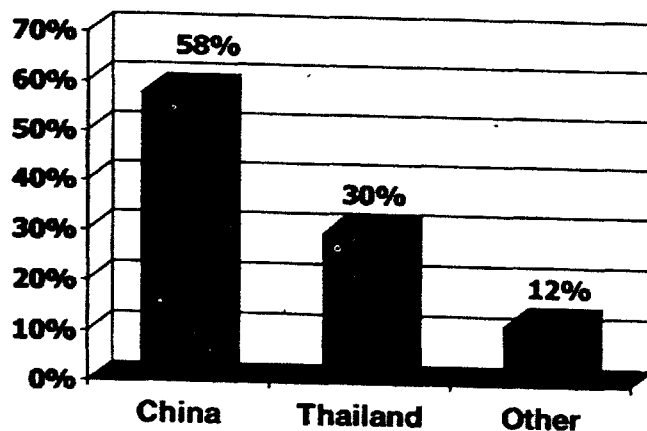
Parcel containing 15 different drugs totaling over 4,500 pills



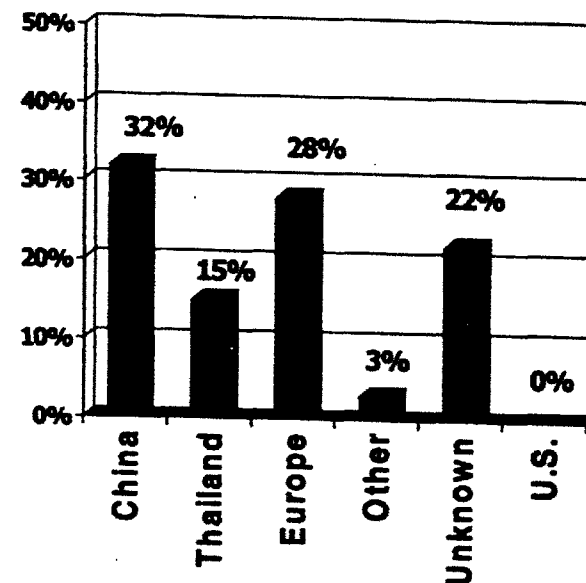
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Operational Stat's - Oakland IMB

Country of Importation



Country of Manufacturer



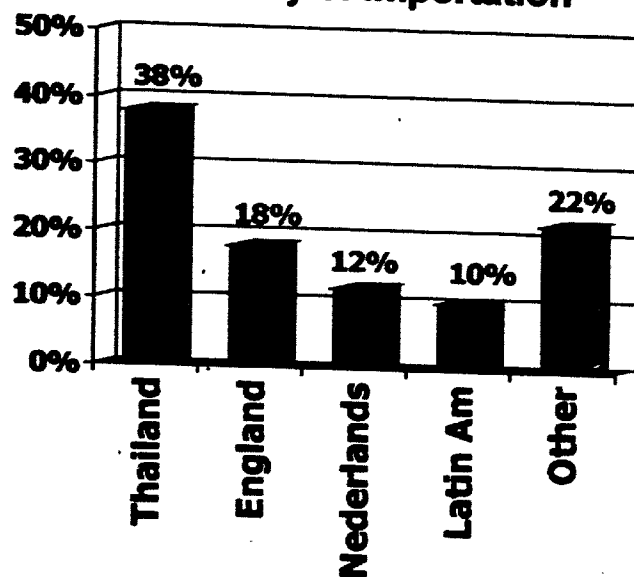
Based on a sampling of
201 parcels from Oakland



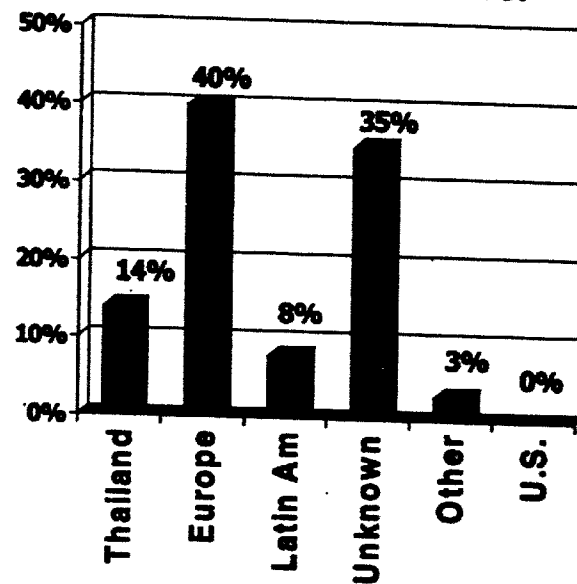
UNITED STATES CUSTOMS SERVICE

Operational Stat's - Dulles IMB

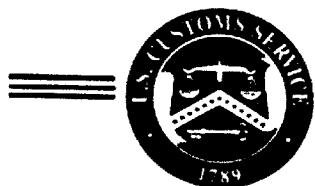
Country of Importation



Country of Manufacturer



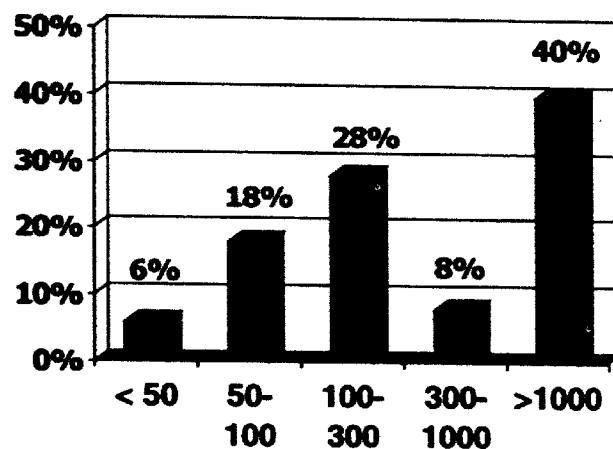
Based on a sampling of
312 parcels from Dulles



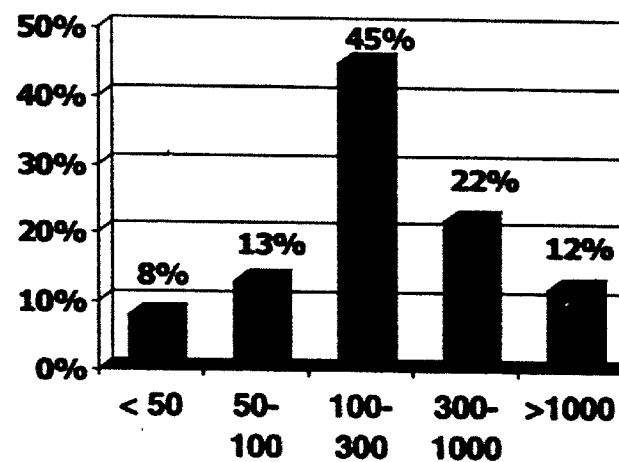
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Quantity of Pharmaceuticals per Parcel

Oakland IMB

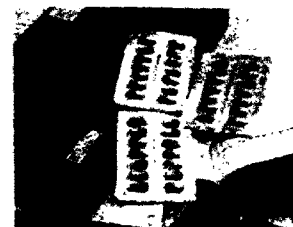


Dulles IMB





UNITED STATES CUSTOMS SERVICE



FDA's Import Guidance

According to FDA's import guidance on prescription drugs, all of the following criteria need to be met for legal importation:

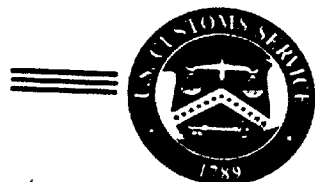
- * Written declaration affirming personal use**
- * 90-day supply or less**
- * Evidence of medical supervision or Rx**
- * Product unavailable in the U.S.**



UNITED STATES CUSTOMS SERVICE

FDA Import Criteria Stat's

	Oakland IMB	Dulles IMB
Parcels Examined	201	312
Number of Different Drugs	642	567
Contains Prescription	1	2
90-Day Supply (<300)	60%	72%
Personal Use Affirmation	0	0
Product Not Available in U.S.	29%	18%
Contains Product Literature (English)	16%	24%



UNITED STATES CUSTOMS SERVICE

FDA's Written Guidance to Customs:

- "It is expected that a Customs officer from the Customs Mail Division will examine a parcel and will set it aside if it appears to contain a drug, biologic, or device.." *

Reality in the Field:

- A very small number of pharmaceuticals are referred to FDA by Customs at the two IMBs. For the most part, if the parcel doesn't contain a scheduled substance it is released back to the Postal Service for delivery

****Source: http://www.fda.gov/ora/compliance_ref/rpm2/ch9pers.html**



UNITED STATES CUSTOMS SERVICE

The Bottom Line.....

- **Over 500 international parcels a week come through the Dulles and Oakland IMBs that contain pharmaceuticals**
- **None of the 512 parcels examined met all of FDA's criteria for the importation of prescription drugs**
- **Over 50% of the pharmaceuticals examined are manufactured in China, Thailand, or of unknown origin**
- **Only 3 parcels contained evidence of medical supervision**
- **48% at parcels examined at Oakland and 34% of parcels at Dulles contain more than 300 pills or capsules**

Mr. STUPAK. Thank you, Mr. Chairman.

So in this recommendation, you have guidelines, do you not, that says—important guidelines on all prescription drugs—all of the following criteria need to be met before legal importation is allowed in this country. Written declaration affirming personal use, 90-day supply or less of medication, evidence of medical supervision or prescription, and product unavailable in the United States. Correct?

Mr. HUBBARD. That guidance is limited to unapproved drugs for serious and life-threatening diseases. It is a tiny number of drugs.

Mr. STUPAK. What percentage of what we are seeing coming into this country would be taken care of just with the enforcement of this guideline?

Mr. HUBBARD. Enforcement of that guideline would presumably exclude 99.9 percent.

Mr. STUPAK. So why don't we just enforce the guideline that is on the books?

Mr. HUBBARD. Because we have to physically receive the drug from Customs. I am sorry, Mr. Stupak, but we have to do that. It is required by the statute.

Mr. STUPAK. Mr. Hubbard, we have seen the video. We have been there. When that parcel comes through the mail and you look at it, either the Custom agent or yourself or me, if it doesn't have the written declaration affirming personal use, if it is more than 90 days, if there is no evidence of medical supervision or prescription, if the product is available in the United States, you could automatically reject it without having to go through all these hurdles that you gave us.

Mr. HUBBARD. But understand, Mr. Stupak, we open this package. It doesn't have those things in it. So the idea is you send a note to the person and say do you meet the requirements? Can you demonstrate to us that this is a legal product or you meet the requirements? Then that person has an opportunity to come back and explain to the FDA.

Mr. STUPAK. Why is the burden on the person who is supposed to be receiving it, and not on the shipper? If you put the burden on the shipper, and if 99.9 of them don't meet these four criteria, why can't you just ship it back?

Mr. HUBBARD. Again, I have to fall back on the wording of our law, which requires us to give notice to the recipient that we have held the drug and not allowed it to move on to the recipient.

Mr. STUPAK. Same question, just a little different, Ms. Durant.

You have 13 mail sites. One mail site being Oakland. When they get this stuff through the mail, they just send it back, don't they?

Ms. DURANT. Yes, sir.

Mr. STUPAK. So if one out of 13 sends it back, why can't all 13 send it back?

Ms. DURANT. One of the problems that we have faced is non-uniformity, which is one of the reasons we have gone to the FDA for a uniform national standard. We should not be sending it back, according to the FDA.

Mr. STUPAK. But if Oakland is sending it back, is Oakland doing it right then?

Ms. DURANT. No.

Mr. HUBBARD. No.

Mr. STUPAK. So the other 12 are doing it right, Oakland is doing it wrong?

Ms. DURANT. According to FDA guidelines.

Mr. STUPAK. According to their guidelines.

Ms. DURANT. To their guidelines.

Mr. STUPAK. Has FDA told Oakland that they have got to keep it all there for them? Have you told them that?

Mr. HUBBARD. We have now.

Mr. STUPAK. You have now. Since when? This morning or Monday?

Mr. HUBBARD. Just recently we learned of this. There has been a fair amount of discretion among the districts for this.

Let me explain it. Historically, Mr. Stupak, this was a small amount of mail. An investigator could look at it and make some judgments about safety.

Mr. STUPAK. Two years ago, we told you this was a small problem that was growing. Two years ago you did nothing. Last year we got up to 455 websites. Today we are over a thousand. We keep telling you, and we keep getting nothing in return.

You are right. It was a small problem with myself, Mr. Waxman, Mr. Dingell, some of us pointed out 2 years ago. So see, your small problem has become a big problem. I just for the love of me can't figure out why your guidelines are not enforced. If one facility is sending it back, why aren't all 13 sending it back? Then we wouldn't be here. We would not be having this hearing, and maybe the Rode's young man would still be with us.

Mr. HUBBARD. The Oakland process was not sanctioned by our folks in headquarters.

Mr. GREENWOOD. The time of the gentleman has expired.

The Chair recognizes the gentlelady from Colorado for 5 minutes.

Ms. DEGETTE. Mr. Hubbard, you just told Congressman Stupak that you had asked Secretary Thompson verbally and in writing to do this new policy which we are all hopeful could happen, this policy. Then when Mr. Stupak said can you submit it to this committee, you said "I will determine if I can do that." What would be the barrier?

Mr. HUBBARD. If there is some need for discussion with the committee about whether this is—

Ms. DEGETTE. Let me be clear. We would like a copy of the written request you made to Secretary Thompson for this new policy. Would that be—

Mr. HUBBARD. I will certainly ask Secretary Thompson today to give it to you, absolutely.

Ms. DEGETTE. Well you sent it to him, I assume. Didn't you say you made a request of the Secretary?

Mr. HUBBARD. Generally I think we would want the recipient to concur with that. But we will.

Ms. DEGETTE. Yes, we would like to have it, if possible. Thank you.

Now I am glad about this policy about the importation, or just stopping all of the drugs. I think that is what you are going to have to do. Unfortunately, I could not go out to Dulles with my colleagues. I had to go to Denver that day. But just watching this video and listening to the testimony, I mean it is a problem that

you can't even get your arms around. It seems to be worsening every day.

So I really think this is an important policy. I agree with my colleagues, it should be implemented right away. I mean the agency should work on it. Congress should work on it. We should all work on it.

Here is the concern I have. I am wondering if you can tell me how this will work, Mr. Hubbard. You said that you would stop all of these drugs except for drugs needed for compassionate care. I am concerned about compassionate care just like everybody else. But listening to that, I was very concerned that that could be the exception that overwhelms the rule.

I will give you an example. How do you know that those yellow pills you had up there that you can't identify won't be considered by someone to be for compassionate care? What standard? I mean it seems to me to be one of those bureaucratic loopholes through which you are going to let all the drugs come in.

Mr. HUBBARD. I think Mr. Stupak read some of the requirements of the current policy which would be applicable, such as that the person have a serious and life-threatening disease.

Ms. DEGETTE. Okay. When all of these drugs come in from overseas, how are you going to apply that policy to them? Won't you be back in the same box you are in right now?

Mr. HUBBARD. We will have to work out a system. Perhaps, for instance, we could request that any such drugs come in via the Federal Express process or one of the common carriers, and have some sort of indicia on it so that Customs knows that this one has pre-clearance by the FDA. These things can be worked out.

Ms. DEGETTE. Well, I am concerned that we are supposed to have a policy right now, and it seems like that is not working out. Wouldn't all of the people sending the drugs simply start putting a statement on there saying "for compassionate use," a declaration.

Mr. HUBBARD. What we would do is we would ask the patient to go to our physicians at our drug center and say I want to go get this drug from a foreign country. It is unapproved. I have this condition. May I do so? It is what we call an IND.

Ms. DEGETTE. How are you going to separate that out from all of the rest of the drugs coming in?

Mr. HUBBARD. Then a thing that had that permission could have some sort of a note from FDA or indicia or something. We can work that out and make sure that that doesn't get intercepted.

Ms. DEGETTE. My recommendation would be that that would be as narrowly drawn and easily identifiable by the Customs agents as possible.

Mr. HUBBARD. Of course.

Ms. DEGETTE. Ms. Nagel, I am wondering if you can comment on whether you think a policy like that could be practicably enforced as all of these drugs are coming in.

Ms. NAGEL. I think that if we have something in advance, something that is easily recognizable, there will be attempts to evade it. There are always attempts to evade whatever enforcement sort of action we have. But I do believe that having the ability to free up our resources on the ones where we are supposed to hold them but we can't—

Ms. DEGETTE. Right. So you think it could actually help improve your job.

Ms. NAGEL. I think it will help, absolutely.

Ms. DEGETTE. Okay. Now, Sergeant Gibbs, I wanted to ask you about something. I want to ask Ms. Nagel as well. A lot of folks have talked about these pharmacies in Mexico. You can just walk in and buy anything. I have a constituent who just came in to see me. He has this horror story that none of us ever want to live through as a parent. His kid went down to Mexico. The roommate said just go into a pharmacy and buy this controlled substance for me, and it is legal in Mexico, so no problem.

So the kid walked into the pharmacy, bought the controlled substance, no problem. Walked out of the pharmacy, and was immediately arrested by the Mexican authorities in a sting operation, and to this day is still sitting in a Mexican jail.

My question to you, I mean there are a whole lot of disturbing ramifications to this story. One is these poor American college students who don't seem to understand the repercussions. We keep hearing though that these are basically sources for free flow of drugs across the border. I am wondering what the enforcement efforts of the Mexican government have been, and if there is some way we can enter into some kind of international agreement to get these pharmacies shut down, or at least to have improved enforcement?

Mr. GIBBS. When I was in Tijuana in April, the proliferation of the pharmacies are all over the border. There were policemen, uniformed officers outside these pharmacies. I saw no one questioned. I saw no one apprehended by these officers. I really don't know what undercover operations are taking place.

I went into one pharmacy and said, "Could I have some Oxycontin, please?" He hesitated. He looked me up and down for a minute and said, "No." I guess I looked like a cop. But there was a guy behind me, walked into a little shop that was selling handbags. He asked the proprietor for MS Contin. That man said, "It is in the back." So he went in the back.

Ms. DEGETTE. So the story that my constituent tells me would be an anomaly in your experience?

Mr. GIBBS. I couldn't answer that question. I don't know.

Ms. DEGETTE. Ms. Nagel, maybe you can.

Ms. NAGEL. The Mexican government, like our government, is taking under the new president, some very affirmative actions. We are actually fairly optimistic that we can see more cooperation in this area. There are circumstances where they have specifically targeted the pharmacies that they believe are just giving out controlled substances without any legitimate need. They are also, as we are, trying to stem the flow of illegal drugs.

The one point that I would like to make, if I could address something Mr. Burr made, the information that we have received about the Oxy coming over in the recent surveys are specific to three different people. My best recollection was each one was listed as having had a prescription.

So under those circumstances, they would not have been brought in under the 50-dosage unit exemption. They would have in fact then come in under a prescription. So there is a lot of confusion as

to when something comes in, when it is in a policy and not in a policy. I think that is where we and the Customs Service are working diligently to provide clear guidance to the inspectors for someone who has a valid prescription can obtain it, and in fact come back. Those that do not will be scrutinized, so that they don't believe they can go over and get anything they want on a day trip and come back with it.

Mr. GREENWOOD. The time of the gentlelady has expired.

I just would ask one question of Ms. Nagel about Oxycontin also. Just as an illustration of how addictive this drug is and what a problem it is, we had Sergeant Gibbs talk about 50 deaths in Virginia. In my district, Bucks County, Pennsylvania, outside of Philadelphia, we had a physician arrested. He had written 1,200 prescriptions for Oxycontin and Xanax in a 4-month period. He was writing them for children as young as 15 years of age. I am reading from the Philadelphia Inquirer.

Investigators said they visited his office at such-and-such an address several times, observing male and female patients crowding a waiting room for hours to get prescriptions for the medications, paying \$59, \$66 in cash for office visits that usually involve no examinations. Most of the patients were gaunt. Their eyes were dilated, and their faces were sunken, like they were on drugs, and irritable as if they were going through withdrawal. So imagine one physician's office in my little neck of the woods. This is a gigantic problem.

You mentioned in one of your statements that if you had evidence of this stuff coming across the border in significant measures from Mexico, that the DEA was prepared to take drastic action. Can you tell us what you mean by that?

Ms. NAGEL. I have spoken to the company. I have discussed with them if we get the evidence that in fact it is coming back, it is being reimported, I can request that they stop shipping it to Mexico. To do that, I need the evidence. I also think it is important, sir, that I address with you I share your concerns.

Before taking this job, I had the State of West Virginia as one of my areas of responsibility. It is one of the States that is seeing the most wide abuse of Oxycontin. As a result, DEA has done something we have never done before. We have created an action plan on a specific narcotic drug. It is not on a class of drugs. It is not on Oxycodone. It is on Oxycontin, the drug itself.

DEA Chief of Operations has signed it. We are actively engaged in trying to determine, through enforcement and intelligence, regulatory administration, industry cooperation, awareness and outreach, we are literally trying to find out exactly what the extent of the problem is. It is huge, because the information we are getting from the narcotic treatment programs is frightening. It is absolutely frightening that they are being overwhelmed with their patients being addicted to Oxycontin.

So please do not ever think that I tried to belittle or minimize the dangers from Oxycontin, because that was not my intention. But what I need is evidence. I need to take steps based on facts and evidence. The agency is more than ready to do that.

Mr. GREENWOOD. If I may, I had no intentions of minimizing your concern about this, but what I do want to know is what do

you mean by needing evidence? What evidence do you need? It seems like it wouldn't be very difficult to find. Sergeant Gibbs walks down informally and found a lot of evidence. A lot of staff have gone down and seen plenty of evidence of Oxycontin coming across the border. What do you need?

Ms. NAGEL. Well, so far I have the one case that I am aware of from Virginia that caused us to ask the company to change the indicia, to stop shipping the 40's, to move the 40's in. I think that was a reasonable action as a result of one investigation.

We have also gotten anecdotal information from the Customs Service and other people that they are seeing it come over. Short of Dr. Shepherd's recent study that showed me three instances of it coming over, that is what I have. I need to know exactly how much is coming over. The Customs Service has assured me they are going to provide that kind of information.

I have gone to my country attache in Mexico. I have asked him for specific information on abuse and diversion within the country. I have gone to my diversion investigators, and to my intelligence people in the agency. I have asked them to get me comprehensive information on the abuse and diversion within country, and what they perceive is coming back.

As a result of that, if I get something that candidly is reasonable, I can then go to the company and first ask them. I believe they will voluntarily do so.

Mr. GREENWOOD. This is some language that we picked up on a chat center from someone who says, hydrocodone, Oxycodone, morphine are all available in Mexico. It says the key here is to make a project out of it. Look around. Ask questions of the pharmacist. What doctor would he recommend for chronic back pain, headache, tooth pain, et cetera. It says I am looking right now at three boxes of 40-milligram Oxycontin I obtained from a medium-sized pharmacy after getting the "in" with a local doctor. So a lot of other stuff in the backroom, morphine being one of them.

So it seems like the evidence is overwhelming. I am not going to press you any further on it. But it wouldn't seem to us that it would take very long to get the evidence that you need to take the drastic actions that you have taken. It is not dramatic to say that lives are in the balance on a daily basis over this one drug.

Let me just ask you this question. If you have an action plan for this one drug, and that is impressive and that is appropriate, can that action plan not include zero tolerance for Oxycontin coming across the border in any number at all?

Ms. NAGEL. To do zero tolerance, sir, again, there are people who have a legitimate medical need to have this drug.

To say that everybody coming over the border does not have a legitimate medical need is not appropriate. What we need to do is take the laws as written and enforce them, and to ask people why you need it, why you're coming over and what is the legitimate need for the drug. Once that's done people that are trying to subvert it or someone on their roller skates isn't going to be permitted to bring in 50 dosage units and that's what we're working with the Customs Service on is trying to say here's the law, here's the policy, here's the guidance, ask the questions—

Mr. GREENWOOD. Let me ask this. Do you have any evidence of Americans who have legitimate prescription for Oxycontin going to Mexico, buying 50 doses or fewer of Oxycontin and coming back and taking that medication as per their doctor's orders?

Ms. NAGEL. I have no specific information, no sir.

Mr. GREENWOOD. Okay, so in a perfect world we might behave in one way, but in the real world we've got, it seems to me, tons of evidence of Oxycontin killing people, being abused on a daily basis all over this country and coming across the Mexican border by the truckload and no evidence of legitimate use of Oxycontin and a decision has to be made using good judgment. I hope and expected that you'll do that and you'll do that very soon.

We would also like you to submit a copy of that action plan to the committee for our record. I thank the witnesses for this Panel again.

Mr. BURR. Mr. Chairman?

Mr. GREENWOOD. Oh, Mr. Burr has another question.

Mr. BURR. If I can be recognized for 1 minute.

Mr. GREENWOOD. Without objection.

Mr. BURR. Ms. Nagel, you said that what you wanted to do was follow the law. The scenario that you described to us of product manufactured here, sent to Mexico was brought back into the country. You do understand that that is against U.S. law today?

Ms. NAGEL. If it is smuggled back into this country, sir, it absolutely is against the law.

Mr. BURR. The reimportation of any drug manufactured in this country, based upon U.S. code is against the law.

Ms. NAGEL. Sir, if the individual is bringing it back into this country for legitimate personal use, my understanding is, sir, that is legal.

Mr. BURR. And I would ask you to meet with Justice, get them to interpret the patent protection that exists in U.S. Code that does not permit the reimportation of pharmaceuticals.

Ms. NAGEL. Yes sir, I'd be happy to.

Mr. BURR. Because I think that if we look at that, the patent protection laws trump everything right now until we change that. We had this discussion with Customs officials last year. It is impossible to expect that Customs can sit at the border and determine whether that product was manufactured here or manufactured anywhere. Members of this committee have looked at the pills that have come out of China, that it is impossible without the expertise of an FDA official to test something and know whether there's actually an active ingredient in it or not, but there's one thing that I rest assured have researched and that is that U.S. code today makes it illegal to reimport products manufactured in this country. If it happens today, then we have flatly turned our backs on it and I would ask you to research that just for your own purposes.

I want to say one precaution to my colleagues and to everybody here. Oxycontin is used in this country by many individuals with cancer as a pain relief pharmaceutical. My understanding is when taken as it's supposed to it is certainly not as addictive as the crushing and the inhaling that the sergeant described to us and it is a vital therapy for those cancer patients. So I don't want every-

body to rush out and demonize this one product because there is a need for it.

Let me also remind you that sometimes just the surroundings suggest what the problem is. In Tijuana today, it's believed there are 1,000 pharmacies. Now with a population of 1.3 million, that's one pharmacy for every 1300 people.

In San Diego, California there are 125 drug stores. That's one drug store per 10,800 residents. Just on the surface, I think we can see that in fact there's every attempt to circumvent the process and to make sure that the supply exists to come back into this country.

I thank the Chairman for the time. I yield back.

Mr. GREENWOOD. The Chair recognizes the gentleman from Florida ready to inquire. If not, this gentleman from Florida would be happy to give you some preparatory time.

Mr. STEARNS. Yes.

Mr. GREENWOOD. Okay.

Mr. STEARNS. I ask for unanimous consent just for a minute, just one follow up question.

Ms. Durant, you mentioned, I guess Mr. Hubbard did as well that the open facility has a different procedure than the other 11 facilities. They're just sending everything back right now, is that accurate?

Ms. DURANT. They're not today. They were sending everything back.

Mr. DEUTSCH. For how long was that going on?

Ms. DURANT. Over a year.

Mr. DEUTSCH. We're talking about tens of thousands of packages that were just going back. I'm just trying to get a sense.

Ms. DURANT. It would be many packages, yes.

Mr. DEUTSCH. How did they distinguish between supplements and prescription drugs? What was going on at that facility?

Ms. DURANT. There was no distinction. It all went back, unless it was approved by FDA.

Mr. DEUTSCH. It's just for 12 months it's going on, were you getting complaints, was anyone getting complaints that they're receiving their supplements or anything?

Ms. DURANT. No.

Mr. DEUTSCH. And tens of thousands of packages, no complaints. Okay, all right, thank you.

Mr. GREENWOOD. The Chair recognizes the gentleman from Florida, Mr. Stearns, for 5 minutes.

Mr. STEARNS. Thank you, Mr. Chairman. This is a question that is directed to Ms. Nagel. The DEA personal importation regulations are important—are, let's see—an importation of controlled substance for personal use cannot be admitted unless it is authorized or permitted by the Federal laws and State laws. Is that true?

Ms. NAGEL. Yes sir.

Mr. STEARNS. The Food and Drug and Cosmetic Act is a Federal law that prohibits importation of drugs that are misbranded, adulterated or unapproved. Controlled substances from Mexico are misbranded because they have labeling in Spanish. Controlled substances made in Mexico are unapproved because they have not been cleared by the FDA. I understand that both Texas and California laws prohibit importation of controlled substances. Given the

requirement that importation must be authorized or permitted under Federal and State laws and the fact that by definition these controlled substances would not be authorized under either FDA or State law, doesn't the DEA's current regulation prohibit the personal importation of controlled substances regardless of the amount?

Ms. NAGEL. No sir, when it comes to the personal importation of controlled substances, both laws apply. There's no conflict between the Food, Drug and Cosmetic Act and the CSA. They're both designed to protect the public health and safety.

In the Controlled Substance Act, Congress explicitly addressed the personal importation exemption. DEA's regulation implements that statute. It's only when FDA advised Customs that the importation of the drug should be disallowed under the FDCA would the importation be disallowed.

Going to something that Mr. Barr said and I will go back to the lawyers, it's my understanding—

Mr. BURR. Burr.

Ms. NAGEL. Don't tell me I need glasses already. I apologize. I will have to find out on this specific instance, but from talking to the lawyers because Congress explicitly addressed the importation in the Controlled Substance Act and permitted up to 50 dosage units for legitimate travel with a variety of things that need to be met, it's my understanding that the Controlled Substance Act applies. I don't know about the patent law, sir. I don't know.

Mr. STEARNS. Well, staff seems to indicate that this is not true, that more than a certain amount is under your authority. Let me just hold for a second because there seems to be a conflict what staff understands and what you're saying.

[Pause.]

More than 50 doses under the current regulations are prohibited.

[Pause.]

It does not speak to less than 50 doses. Does that make sense to you?

Ms. NAGEL. If I could try? This is one of the few times in my life I wish I had a lawyer with me.

Mr. STEARNS. Me, too.

Ms. NAGEL. If I could try to do this. The way the law is written to permit international travelers who have a legitimate need to have medication with them, the law permits you to bring up to 50 dosage units.

Mr. STEARNS. Without any kind of check or anything?

Ms. NAGEL. Correct. Without a prescription, without—

Mr. STEARNS. Where does it say that? Because a person could go 50 times with under 50 doses and be able to get these drugs.

Ms. NAGEL. The problem is with the implementation of the policy to enforce the law. The law does not say you can go 10 times a day. That absolutely is not in the spirit of the law. The spirit of the law is to allow an international traveler with a bona fide need to bring something back that will get them home until they can get medical attention. That's not the way it's been interpreted and it's not being enforced and that's what we're working with the Customs Service so we don't have someone coming back on roller skates. But if someone comes back in without a prescription, they're asked the

legitimate questions and if they don't have the right answers, it does not come in.

Mr. STEARNS. Well, I'm reading from the Controlled Substances Import and Export Act. Section 1007 and it mentions the statute in accordance with applicable Federal and State law they may not import the controlled substance into the United States in an amount that exceeds 50 dosage units of the controlled substance.

Now just what that says, it's not saying that it can come in with less than 50, so you're making a policy decision.

Ms. NAGEL. It's not a policy decision, sir. In the law, the way again I understand it is, it says if I can—a U.S. resident who enters the United States who does not possess a valid prescription may not import exceeding 50 dosage units.

Mr. STEARNS. And then you assume that somebody could come in with less than 50, 40?

Ms. NAGEL. If, in fact, they can demonstrate the personal medical necessity, it's in the original container, the trade and chemical name appears on it, they can demonstrate the valid need for it, yes. It doesn't mean no questions asked. Anything comes in, it means if you have a need, you can bring in what you need to get home.

Mr. STEARNS. But in my first question to you I was giving you the State laws in California and Texas that prohibit importation of controlled substances, so what you're doing is preempting State, California and Texas laws?

Ms. NAGEL. I wouldn't want to say that, sir, without talking to my lawyer.

Mr. STEARNS. But that's what you're saying by saying that you interpret this to mean that they can come in with less than 50 doses.

Ms. NAGEL. If they meet the requirements of the statute and the requirements of the regulation and they can demonstrate the personal necessity, the Controlled Substance Act permits the entry.

Mr. STEARNS. And I think you would agree though that Texas and California is interpreting this different.

Ms. NAGEL. I don't know, sir, and I would be more than happy to come back with more information, being the only one who didn't come with a lawyer, once again, that was a major mistake in judgment.

Mr. STEARNS. What staff is contending is that under State law there is a requirement and it's not interpreted that people can come in with under 50 doses. So what you're doing by interpreting that, you're opening it up and a person can come in 50 times with under 50 doses and do that. What is the number that the person can do before they are against the law, in your opinion, 5 times, 10 times, 100 times—

Ms. NAGEL. Sir, this is not for someone to be making day trips. It never was implied—

Mr. STEARNS. But you and I both know people make day trips.

Ms. NAGEL. That's why we're working with the Customs Service so that they understand exactly what the policy is, exactly what the law is, the questions to ask to ensure it's implemented appropriately and people are not waived into the country because you have 49 or 50 of 10 different substances. That's exactly what we're working actively on now.

Mr. BURR. Will the gentleman yield?

Mr. STEARNS. Just 1 second. Would you admit that the person would take more than one trip in a day?

Ms. NAGEL. Can a person? Absolutely.

Mr. STEARNS. Could they take more than two trips?

Ms. NAGEL. Sir, anything is possible.

Mr. STEARNS. They could then skirt the law that you just interpreted this way.

Ms. NAGEL. If they were—if they declare it, which is part of it, they declare it, they talk to the Customs Inspector, they explain what their personal need is, I don't believe that drug would be permitted to come into the country.

Mr. STEARNS. See, no one keeps track of it. For example, if I get a prescription under Blue Cross or with my doctor, if I try to get a prescription for more than let's say, let's say I get a prescription for 60 days and at the end of 30 days I try to get another prescription for 60 days, I can't do it because you can't have too much of this drug. Now in some cases if I pay for it myself, I can. So the pill instead of being 50 cents becomes \$5, so my point is that the way you've outlined this is it's sort of a loophole and I think in Texas and California that they have laws that prohibit the importation of controlled substances and so I think that's an area that Mr. Chairman, I think they should clarify and if they don't, Mr. Chairman, they probably should come back in writing to us.

Ms. NAGEL. I'd be happy to, sir.

Mr. STEARNS. That would be helpful for us and I yield my time.

Mr. BURR. I was only going to point out to everybody who's on the panel. I know each one of you individually thinks you're very specific on what you've asked Customs to do. In many cases, there are other laws on the books in the State of California and in Texas that sort of run opposite, but one of the things that I've heard from Customs last time they were in, this time, is that they don't understand what they're supposed to be doing. Today, you brought specificity to it. My only hope is that when you leave, we will all push the Secretary to adopt this. If it needs legislation, legislation; if it needs regulation, regulation. Let's ram it through as fast as we can. Let's prove that we can address a problem just like the FDA approved a leukemia drug in 2½ months and let's close this up so we don't have this worry any more. That's the specifics that we need so that Customs knows how to do their job, so DEA can confidently address the legal side of it that is so rampant in every community.

I'd yield back.

Mr. STEARNS. Mr. Chairman, I thank you for your courtesy and I yield back.

Mr. GREENWOOD. The Chair thanks the gentleman and thanks the witnesses and would care to remind Mr. Hubbard that pursuant to Ms. DeGette's request, the committee asks for a written copy of the recommendation to the Secretary and these witnesses are excused. Thank you.

The Chair then calls Panel 3, our final Panel to come forward: Mr. James Christian, Vice President and Head of Global Corporate Security at Novartis International AG; Dr. Marvin Shepherd, Professor, College of Pharmacy, University of Texas; Dr. John Glover,

Vice President, Corporate Security, Bristol-Myers Squibb Company; Mr. Gene Haislip of Leesburg, Virginia; Mr. Donald deKieffer of deKieffer & Horgan and Mr. William Trundley, Vice President, Corporate Security and Investigations at GlaxoSmithKline.

—The Chair welcomes the witnesses and thanks them for their patience for the past 4 hours. You are all aware that this committee is holding an investigative hearing and when doing so has had the practice of taking testimony under oath.

Do any of you have objections to taking, giving your testimony under oath? Seeing no objections, the Chair then advises that under the rules of the House and the rules of the committee you are entitled to be advised by counsel. Do you desire to be advised by counsel during your testimony? In that case, will you please rise and raise your right hands and I'll swear you in?

[Witnesses sworn.]

Thank you, you may be seated. You are under oath and we will begin with Dr. Shepherd. You are recognized, sir, for 5 minutes for your testimony.

TESTIMONY OF MARVIN SHEPHERD, PROFESSOR, COLLEGE OF PHARMACY, UNIVERSITY OF TEXAS; JOHN D. GLOVER, VICE PRESIDENT, CORPORATE SECURITY, BRISTOL-MYERS SQUIBB COMPANY; JAMES CHRISTIAN, VICE PRESIDENT AND HEAD OF GLOBAL CORPORATE SECURITY, NOVARTIS INTERNATIONAL; WILLIAM TRUNDLEY, VICE PRESIDENT OF CORPORATE SECURITY INVESTIGATIONS, GLAXOSMITH KLINE; GENE R. HAISLIP, CONSULTANT; AND DONALD deKIEFFER, deKIEFFER & HORGAN

Mr. SHEPHERD. Thank you, Mr. Chairman. I hope to give a pretty clear testimony and I hope to also clear up some what I consider false statements being made earlier today. Well, maybe not false statements, statements that are not true in the State of Texas or in Mexico, the way I understand it. I hope we can get some clear air here on what's a prescription and what's required in Mexico and what's not, get that done.

Let me begin. My name is Marvin Shepherd. I'm from the University of Texas. I've been interested in this problem of importation of pharmaceuticals into this country for about 8 to 10 years now. It all came about because of some problems with U.S. pharmacists when people from Mexico or U.S. residents would go to Mexico and buy a bag load of drugs and then bring them in or cross the border and land on to the U.S. pharmacists and say tell me how to take these and what are they for? And that's when I first got notice of the wind of the problem because they didn't have any instructions, everything was written in Spanish and it was a real problem.

So it's a pleasure to be here and I find it striking that before the Internet pharmacy operations really no one cared and everyone seemed to blame the importation of pharmaceuticals a border problem. Well, I'll tell you right now, it is not a border problem and the Internet really emphasized that. It was not a border problem before because in my study in 1995, 40 percent of the drugs purchased out of Nuevo Laredo were going outside of Texas. They went as far away as Maine, Michigan and Washington, Virginia, you name it. They went there and that's 41 percent of all males who went down

there out of State and 20 percent of all females who went down there and bought drugs in Mexico our out of the State of Texas. They were not part of the community. Now admittedly, 60 percent of all the other purchases down there were from the State of Texas. Sixty percent of all the purchasers were from the State of Texas down there. So we faced this problem for a long time and we've been struggling with the controlled substance incidents and the problem and we've even prosecuted a lot of people coming across the border with Ritalin, Valium and Neopercodan and the whole works.

We've been turned down by Federal courts too, on that.

But I want to reemphasize that I invite any and all of you to come down to a border town. You won't believe it. Farmacias are a major tourist attraction in any border town. They're on every corner, every other street and the major purchaser of the drugs are U.S. residents. You walk in any of them and you talk to the owner, the owner will say 95 percent of the people who purchase drugs here are U.S. residents and that's what they're made for. It's a huge economy and if we look at the 15 drugs that I found, the top 15 drugs coming across the border in 1995 were all controlled substances. The volume of those 15 drugs is \$135 million just in 1997. It was 6 percent of the total Mexican drug distribution right there. Six percent coming out of a little town called Nuevo Laredo. I don't even want to think about what's coming out of Juarez or Metamoras or Tijuana because those have got huge volumes. In Nuevo Laredo, they have maybe 25,000 to 30,00 walkovers on a Saturday afternoon and about an estimated anywhere from 25 to 40 percent of those walkovers are coming back with a pharmaceutical product. So it's a big business and I feel sorry for U.S. Customs when they've got two people scanning people who come across and the line is from here to the parking lot getting back into the check point. It's impossible to check them all. They're just lined up and it takes more than an hour sometimes to get through the border at 5 o'clock on a Saturday afternoon standing in the hot sun trying to across. It's a huge problem and it's a big business. Huge business for the Mexican economy.

There are three major reasons and I'll give my opinion as to why they do this and it's not price is the No. 1. The No. 1 reason why U.S. residents go to Mexico is easy access. Very easy access to prescription drug products. Mexico has two drug products, basically, an over-the-counter drug product which includes antibiotics, all your cardiac medications, all your cholesterol drugs, all your GI tract drugs, birth control, estrogen compounds and some steroids. They're over the counter. As recorded earlier, they sell those like candy and gum. So if you want tetracycline, erythromycin, ampicillin, Claritin, Claritin-D, Allegra, you name it, you can get it over there without a prescription, without anything, just ask for it. Many of the pharmacies over there will have an American PDR, Physicians Desk Reference on the counter, along with the Spanish or Mexican references. Oh, I don't remember the name of my drug and he'll say well, go over there and find it and I'll see if I can find the equivalent drug here. Sometimes they're lucky to find equivalent drug, sometimes they cannot find the equivalent drug, but they'll find the next best one they can for that product and they'll

say well, by the way, while I'm here, Aunt So and So needs this and my neighbor or here needs this and my other friends over there need this and I also need some tetracycline, hopefully not for their children, but I also need erythromycin or ampicillin for colds that pop up in my family. And they purchase it all. That's not talking about the controlled substance. That's just talking about prescription drugs.

I want to emphasize one other point for you. I'll bet you 98 percent of those prescription drugs are not FDA approved. I've got a list of the FDA-approved drugs coming out of Mexico right now and there's about 12 and most of those are in bulk form. I don't know if it's the finished product or not. They're not FDA approved, so what FDA was saying earlier about what's the quality of these drugs, they don't know. I don't know. No one knows because they haven't fit the quality standards of what those prescription drugs look like. So easy access.

If you want to buy a controlled substance and let's clarify the law for the Congresswoman, if you want to buy a controlled substance in Mexico, you have to have a prescription from Mexico. It's got to be written by a doctor in Mexico. The law in Mexico says and the prescription has to be in duplicate form because they will keep one copy in the pharmacy. That's the only thing they really have a record of. They log it into a log book and there's only three groups of compounds. The No. 1 group are injectables, primarily; the No. 2 group of controlled substance are most of what we consider IIIs and IVs in this country, the Valiums, that kind of product, some of the narcotics, Tylenol 3. The third group are some steroids, testosterone and some—I've got a list of them here if you want a list, but those are the three groups. The No. 1, it's pretty difficult to get a prescription from a community pharmacy, but it is possible.

Just recently I saw Demerol come across in 50 ampoules last month and a box of ampoules. Now I don't know if it hits the 50 dosage units or not, but it was a box of Demerol, 50 ampoules and a box of syringes come across the border.

Now the other drugs, as I said, you need a prescription for them. Now when you come across you need two prescriptions, a U.S. doctor, and a Mexican doctor to do it. Now let's get this clear, and I'll be quite frank and I'll probably get shot outside this building, but there's a heck of a lot of collusion going on between the Mexican docs and the pharmacies, a lot of collusion. You go into them and you won't even see the doc, you'll see a clerk who writes the prescriptions. I've been there. I've seen it. Somebody is at the front desk says what do you need? I said I need Rohypnol, Valium, Asylex, you name it and they'll write it for you. As a matter of fact, the last time I was in there he wrote all three of them out on one prescription and gave it to me. He said I recommend you go to the international pharmacy two blocks up on the right.

The next Sunday I went in with CNN News. I went to the pharmacy. I knew the prescription writer was closed. I went into the pharmacy and I said I'll need Valium. I can't remember the other three drugs, I needed. I wrote them on a piece of scrap paper, gave them to a 12-year-old kid. The kid went upstairs and down the street somewhere, came back with a prescription written on one prescription form for three drugs. Then the pharmacist, and it

wasn't a pharmacist either, just a clerk, gave me the prescription and says write your name at the top of this prescription. \$300 later you walk out with them. But they want documentation? Ritalin was the other drug because Ritalin is a popular product coming across.

It's easy and you can see the collusion between the docs are getting their \$30 to \$50 for the controlled substance and the pharmacist getting his money up front on the controlled substance. No directions, no labels, everything is written in Spanish and no one knows how to take it whether it's a controlled substance or a non-controlled substance and it's a huge mill, economic mill for Mexico right now. Huge.

The lower prices. Everybody has talked about the lower prices. Let's—

Mr. GREENWOOD. I'm sorry, we are all fascinated and as a result of that I've been extraordinarily indulgent with the time.

Mr. SHEPHERD. I'll close.

Mr. GREENWOOD. We'll ask you lots of questions, but we need to go on to the other witnesses.

Mr. SHEPHERD. Sure. That's fine. Do you want me to close it or—

Mr. GREENWOOD. Do you have a concluding paragraph, why don't you go there and then we'll get back to you with questions.

Mr. SHEPHERD. Concluding paragraph. You can enforce existing law. I tend to agree with a couple of Congressmen here, the existing law could do the job. I think you need to harmonize. You need to get a group together with the Mexicans and the U.S., harmonize the business. Some kind of panel has got to be put together to look at the problem. No. 3, to stop the diversion, you could ban controlled substances completely. We already talked about that one. No. 4, the public education needs to be done. Most Americans think that if it's made by Eli Lilly or Squibb or Pfizer, whoever it is, it's FDA approved. They think anything with that kind of a label is FDA approved. Even if it was made by Eli Lilly of Mexico City, it's not the truth. That's a false. It's not true at all. And I think we need to teach Customs and FDA people the realities of the real world out there and what's going on.

Customs people cannot make the determination whether it's medical necessary or not or it's compassion. They can't do that. They don't have the training for that. I don't know how they're going to do that and I'll close with that. I'll wish you the best.

[The prepared statement of Marvin Shepherd follows:]

PREPARED STATEMENT OF MARV SHEPHERD, DIRECTOR, CENTER FOR
PHARMACOECONOMIC STUDIES, COLLEGE OF PHARMACY, UNIVERSITY OF TEXAS

INTRODUCTION

It is pleasure being here today to discuss the issue of the importation of pharmaceutical products. I have been involved with this area for close to a decade, but my involvement has been on the issue of Mexican prescription drugs entering the U.S. I find it striking that before internet pharmacy operations, it was difficult to get anyone's interest and attention with the problems of importation of pharmaceuticals from Mexico, but now with the growing international pharmaceutical market via the internet concern for all methods of pharmaceutical importation has risen. I applaud you for taking on the task and looking in depth at the issues and problems created by the importation of pharmaceutical products. There are many social, legal and medical issues to address, but the main concerns I have involve patient safety and

lack of control. People have been hurt and some have died due to the importation of pharmaceuticals. Unless we can find a better method of controlling the problem, more people will suffer.

As mentioned, Texas has faced the problem of drug importation from Mexico for decades but in the last five to ten years the practice has escalated. It is estimated that from 25 to 40 percent of all U.S. residents who enter Mexico bring back prescription pharmaceutical products. Many people repeatedly visit Mexico to obtain drug products for themselves, family and friends. It has also been documented that from one El Paso, Texas clinic serving US residents, over 80 percent of the patients go to Mexico to obtain their prescription drugs. If you want a full perspective of the size of this importation industry, I invite you to visit anyone of the Mexican border towns of Texas. Rows of farmacias line the streets of Nuevo Laredo, Juarez, Reynosa and Metamoras. Farmacias are a major tourist draw for the Mexican economy, especially border town economies.

The customer base for this industry is U.S. residents and it is huge; it is so huge that U.S. Customs struggles with just handling the volume of people. How do check 25,000 to 30,000 people who walk across one bridge and returning the same afternoon? And what about the vehicular traffic? Over a million vehicles cross and return from Nuevo Laredo each month. In 1997, over 7 million U.S. residents used the Laredo border crossing between Mexico and U.S.

The size of the retail pharmacy business enterprise in border communities is huge. For example, the estimated 1997 annual dollar volume for just the top 15 pharmaceutical products entering the U.S. from Nuevo Laredo was \$134 million. This is a conservative estimated because it only assumed 25% of the U.S. residents entering Nuevo Laredo purchased pharmaceuticals. To get a better perspective, this \$134 million makes up nearly 6 percent of the total Mexican pharmaceutical market and this was just for 15 products from one border city. Another view is to look at the volume of drugs. Our research documented a conservative estimated of over 11,000 Valium® tablets were coming across from Nuevo Laredo per day by U.S. residents in 1995. I have do not believe this number has decreased, in fact I tend to think that it has increased.

Don't be thinking that this is a Texas problem or a California, Arizona or New Mexico state problem, because my research documents that 41 percent of males and 27 percent of the females who purchased prescription drugs in Nuevo Laredo were NOT from Texas; we found that these U.S. residents were from 37 states; some were as far away as Washington, Maine, Minnesota and Massachusetts. The Mexican pharmaceutical importation practice has been an ongoing problem and affects more than just border states and communities.

REASONS WHY PEOPLE VISIT MEXICO FOR DRUGS

There are many reasons why U.S. residents visit Mexico to purchase pharmaceuticals. The main reasons why U.S. residents obtain their pharmaceuticals from Mexico are:

- 1.) Easy access to pharmaceuticals,
- 2.) Lower prices for selected drug products; and
- 3.) The drug product is not available in the U.S.

Also, farmacias have done well marketing their products to tourists. They have internet sites, they have put ads in newspapers papers and there have been many magazine and newspaper articles which describe the process and document the cost savings. Few of these articles describe the legal problems nor do they describe the drug safety problems and risks. Let me take a minute to talk about each of these reasons.

EASY ACCESS

Most prescription drug products in Mexico are sold as over-the-counter products. You can purchase antibiotics, high blood pressure medications, heart medications, gastrointestinal medications, antihistamines, birth control pills, plus many other pharmaceutical products without needing a prescription. These products are sold like candy bars and gum are sold in the U.S. In fact, if you do not know the name of the product you want, many of the farmacias will have a *U.S. Physician Desk Reference* on the counter for reference. This compendium list all drugs available in the US. So you can look up the drug you want and the farmacia clerk will try to find the Mexican drug equivalent or a similar product. Many times there is no Mexican equivalent available. Also, please note there are no prescription drug labels as we have in the U.S. No drug directions for use are given, all the products are labeled with the manufacturer's label in Spanish.

Controlled drug substances in Mexico do need a prescription written by a physician practicing in Mexico. However, this requirement is no barrier to purchasers of controlled substances. Some Mexican physicians in border towns have established their practice just to provide prescription for U.S. customers. In fact, they have developed business relationships with neighboring farmacias.

LOWER PRICES

Some Mexican prescription pharmaceuticals do have a lower price with many have a substantial lower price. However, not all Mexican drug products have a lower price and for many products the U.S. prices are very competitive, especially when you compare prices of antibiotic therapies or generic drug prices. For example, the price of Dimetapp® 12 capsules in Juarez Mexico is \$16.15 while the price in the U.S. is \$6.85. Claritin D®, 12 capsules in Juarez is \$16.38, in the U.S. it is \$19.75. An example, of a major difference in price of Vasotec® 10mg in Juarez is \$16.24 and the price in Austin Texas is \$47.88. Overall, prices are cheaper in Mexico, but it is product dependent. The perceived major differences in prices do draw many people to Mexico to purchase pharmaceutical products, especially for those people who do not have limited funds such as those on a fixed income, retired or lack prescription drug insurance coverage.

PRODUCTS NOT AVAILABLE IN THE U.S.

As mentioned, some Mexican pharmaceutical products are NOT available in the U.S. Either the manufacturer decided not to market the product or in some cases the product does not have FDA approval. Examples of Mexican products not available in the U.S. are Asenlix® (clobenzorex a stimulant product), Chloromycetin® (Chloramphenicol®, antibiotic), Ponderex® (fenfluramine, weight reduction), and Rohypnol® (flunitrazepam, sedative hypnotic). Also, some Mexican products are combination products which are not available in the U.S. For example, the product Qual® contains acetaminophen 200mg, Valium® 2mg, and Darvon® 50mg. Except for products banned from the U.S., Customs officials do allow people to bring into the U.S. pharmaceutical products which are not available in the U.S. as long as the patient has proper documentation for using the product. In addition, if people begin a drug therapy in Mexico, they are allowed to import the continuation of such therapies to the U.S.

PATIENT SAFETY CONCERNS

As mentioned earlier, I have some grave concerns about patient safety and the use of Mexican pharmaceuticals. My concerns revolve the lack of medical supervision of the patient's therapy, the patient's lack of understanding on how to use the product correctly and the indiscriminate use of products. Finally, I have a concern about the assurance of product quality. To me, all of these have a potential to harm, severely injure or kill people.

First, the vast majority of Mexican drug products are NOT FDA approved. There are only a handful of products made in Mexico which have an FDA approval and most of these are bulk products and not finished goods. Based on this fact alone, the vast majority of people who enter the U.S. from Mexico with a prescription pharmaceutical product are in violation of U.S. law. The key point I want to make here, is that U.S. customers of Mexican pharmaceuticals need to be informed that foreign made versions of U.S. approved drugs may not have been manufactured in accordance and pursuant to FDA. In other words, the products may not be the same.

The health concern I have is when a U.S. resident, who is successfully being treated and is stabilized on a U.S. manufactured drug product, goes to Mexico obtains what he/she considers to be the identical product, but it is not. The potential harm is great depending on the therapeutic agent and the clinical outcome. Switching back and forth from U.S. made product to Mexican product may be dangerous, especially for those products which have a narrow therapeutic index.

My second concern is the indiscriminate use of prescription products, especially antibiotic products, but other therapeutic agents are also affected. The indiscriminate and self-medication use of antibiotics increase the problem of antibiotic resistance. This has already been documented with the high antibiotic resistance rates for tuberculosis in Mexican border cities. Some U.S. residents visiting Mexico purchase tetracycline, penicillin and erythromycin like candy bars. They save the products and self-treat themselves, family members and friends. Also, with self-treatment, medication compliance is usually lower which contributes to the antibiotic resistance problem. The lack of understanding and the poor use of pharmaceutical products has the potential of seriously affecting the health of many.

As mentioned earlier, when U.S. customers purchase Mexican drugs little if any information is given to the customer as to how to use the product. There are no drug labels giving directions for use and the labels are written in Spanish which may be of no value to some. Thus, the opportunity to learn about the Mexican product is limited. This can be very dangerous for those who want to "try-out" a new product. Final note, few farmacias have a college educated pharmacist on their staff. In fact, farmacias which do not sell controlled substances are not required to have a college educated pharmacist on their staffs. Most farmacias are staffed with clerks, thus limiting the customer's opportunity to get competent help and information about the medication. Even if the farmacias does provide controlled drugs, there is no requirement that a college educated pharmacist must be present. As a side note, upon returning to the U.S., many Mexican drug purchasers visit U.S. pharmacists and inquire as to how to use the products purchased in Mexico.

RECOMMENDATIONS

Enforce Existing Law

The recommendation I want to make is to ban the import of all non-FDA approved pharmaceuticals from foreign countries. Basically, this recommendation is asking for the enforcement of the current written law (Federal Food Drug and Cosmetic, 21U.S.C. Section 331). I realize that this is a difficult political decision, especially with the elderly contingent and those who do not have the financial resources to purchase therapeutic remedies. It would also cause international political problems, especially with Mexico and the NAFTA agreement.

Develop a Strategic Plan to Harmonize Pharmaceutical Business Between U.S. and Mexico

I believe the major problem between Mexico and U.S. on the pharmaceutical trade is the vast differences in regulation, education and professional pharmacy practice. Efforts need to be made to bring health care practitioners and officials together from both countries and develop a plan to try to harmonize the medical and pharmaceutical industries. U.S. residents have been using the Mexican health care system for decades. However, currently, more U.S. residents are taking advantage of and abusing the Mexican health care system for personal gain. Medical and pharmaceutical regulations and practice behaviors within the border communities need to be examined and perhaps modified on both sides to better provide patient care. This is a long term approach and will take a lot of effort, but it is a positive step forward.

Ban Controlled Substances from Entering the U.S., especially from Mexico

While waiting for the long term approach in addressing the professional and regulatory climate between the two countries, my recommendation would be to *try to control the personal import of controlled substances from Mexico*. In my research, it was found that the most popular drugs coming across the border from Mexico at the Laredo border crossing were controlled substances. All of the 15 most frequently declared products entering the U.S. were controlled substances. These included narcotic analgesics (Neopercodan, Nuban Tylex), tranquilizers (Valium), sedative/hypnotics (Rohypnol, Qual, Halcion), stimulants (Ritalin, Tenuate Dospan, Diminix, Aselix) antipsychotic/antianxiety (Antivan), and muscle relaxant (Somalgesic). What alarmed me the most was that the vast majority of these products were imported by people under 35 years of age. If you are worried about the impact such a recommendation would have on the elderly, I can say that few elderly purchase controlled substances in Mexico. My study found that only 0.6 percent of all controlled substances entering the U.S. were carried by someone over 65 years of age.

Although I have not compared the prices of controlled substances between the U.S. and Mexico, it is my belief that the cost differences are small, mainly because most controlled substances in the U.S. are available in generic form. My personal feeling is that much of the controlled substances entering the U.S. are for recreational use and sold on the streets, but I have no data to support the belief. I just question why so many youths travel to Mexico and bring back so many stimulants, tranquilizers and narcotics. Basically, this recommendation calls for a cost-benefit analysis. Does the benefit of allowing the legitimate use of controlled substances from Mexico outweigh the black market and detrimental and addiction effects of recreational drug use? Personally, I do not think so.

Last month I spent a Saturday in Laredo assisting the FDA in collecting data on the type and amount of pharmaceuticals coming across from Nuevo Laredo. I really did not see many changes, of course I saw no Rohypnol®, but I did see tranquilizers (Valium®) and narcotic analgesics (Neopercodan® and Oxycotin®) and most of these were being carried by males in their 20s or 30s.

Develop a Public Educational Program on the Risks Associated with Foreign Medications

My second recommendation is for the development of a major public educational program informing the public about the potential problems which may result with the use of Mexican pharmaceuticals or foreign made non-approved drug products. Currently, the public believes that just because a well-known U.S. based pharmaceutical manufacturer's label is on the product the product is FDA approved. Nothing can be further from the truth. Drug labels in Mexico are similar in size, type, color and style with the U.S. and when the consumer sees Eli Lilly, Pfizer, or any other manufacturer's label they assume it is a FDA approved product. I recommend that a public education program needs to be developed warning them that this is not always the case.

In this recommended educational program, the threat of counterfeit medications from Mexico needs to be highlighted. Recent reports have documented the increasing risk and threat of counterfeit medications coming into the U.S. from Mexico. The public needs to be aware of the problem and the potential risk. In my opinion, I think the threat of counterfeit medications will continue to increase with the high prices of pharmaceuticals. We need to develop better and cost-effective surveillance techniques.

Give U.S. Customs and FDA Technological Support

My last recommendation is to provide assistance to US Customs and the FDA in developing programs to monitor the importation of foreign drug products. Data are lacking on the extent of pharmaceutical products are entering the U.S. from Mexico. I have worked with Customs agents in Laredo and they are overburdened with this problem. The number of people crossing the border is tremendous. In fact, in my opinion they are begging for assistance. They lack the pharmaceutical training, and expertise to identify potentially hazardous prescription drug products. In addition, they lack sophisticated computer technology to collect the needed data to properly monitor the extent of drug importation. They are still using the handwritten form method. New computerized methods need to be developed to improve the efficiency and effectiveness of their enforcement for prescription drug products.

CLOSING

Thanks for asking my input. I'll be glad to work with you and other governmental officials to explore our opportunities to assure quality care and patient safety on the procuring and use of pharmaceutical products. Thanks for this opportunity.

Mr. GREENWOOD. Thank you very much.

Dr. Glover for 5 minutes, please.

TESTIMONY OF JOHN D. GLOVER

Mr. GLOVER. Thank you very much, Mr. Chairman and committee members. My name is John Glover. I'm Vice President for Corporate Security for Bristol-Myers Squibb Company, a worldwide medical and health care pharmaceutical company doing business in over 100 countries. I have submitted a written report for the record, but I'll just make a few brief remarks at this time.

Before I became Vice President for Corporate Security with Bristol-Myers Squibb Company, I had a 24 year career in the FBI, in investigative, administrative and executive positions. My last position in the FBI, I was Executive Assistant Director, one of three positions reporting to the Director. Also, while I was in the FBI I was assigned to the Atlanta FBI Office. During the early 1980's we conducted an investigation of pharmaceutical sample abuse. That particular case we called in Atlanta at the time our farmity case, among other factors, led to hearings on the Hill and the enactment of the Prescription Drug Marketing Act. I have always believed in the strict controls and the flow of prescription drugs are essential to protecting the health and safety of Americans. Concerns about the risk to public safety from adulterated and counterfeit imported medicines, I can tell you, were paramount in the minds of the legis-

lators at the time of the enactment of the PDMA. In my opinion, concerns for the public health and safety of American citizens should continue to be paramount in the minds of this legislature and in any legislation passed by any Congress. I will only make a few points.

Point number 1 that counterfeiting of prescription drugs is a global and growing problem; that pharmacies, distributors and criminal enterprises in Mexico and I agree with Dr. Shepherd are significant sources of the counterfeit and diverted medicines that we find on U.S. shelves and in U.S. medicine cabinets; that factories in India and China are the sources of most of the bulk actives used in counterfeit pharmaceuticals worldwide; that improved technology and the Internet have contributed to the expansion of this trade in counterfeit pharmaceuticals and I also agree that from my experiences that the FDA, the DEA and the Customs Service lacked the resources necessary to police effectively for counterfeit and diverted pharmaceuticals.

As a Security Vice President with Bristol-Myers Squibb Company we formed a group several years ago called the Pharmaceutical Security Institute. The Pharmaceutical Security Institute is an industry body whose primary purpose it is to conduct investigations worldwide primarily addressing the international counterfeiting problem in pharmaceuticals and we've conducted numerous studies and investigations. We've conducted studies in China, studies or investigations in China and India and the Philippines, in Indonesia and South Africa, Europe, South America, Mexico. Each of our studies or investigations have resulted in the findings of the existence of counterfeit and diverted problems in those locations.

So I want to say that there's a major problem of counterfeited and diverted problems out there. What can we and should we be doing to ensure that the problem of worldwide counterfeit and diverted problems did not become a significant U.S. problem. First, we must recognize that the U.S. is the largest and most lucrative market in the world, is the ultimate target, the ultimate target for many counterfeiters and diverters. We must do what we can to make sure that we don't make it easier for these counterfeiting operations than we already have. Therefore, we should continue to maintain our political will and not allow the desire for low cost medicines to undermine our commitment to protecting the health of U.S. citizens. Second, we must ensure that maintain comprehensive legislation to protect our pharmaceutical industry and encourage innovation. Third, we must aggressively enforce the laws to combat the trade of spurious medicines. And then last, we must maintain strong penal sanctions against individuals convicted of violating the various drugs laws.

That's the end of my brief remarks, Mr. Chairman and committee members. Thank you for the opportunity to express my view on this important subject.

[The prepared statement of John D. Glover follows:]

PREPARED STATEMENT OF JOHN D. GLOVER, VICE PRESIDENT, CORPORATE SECURITY,
BRISTOL-MYERS SQUIBB COMPANY

Good morning Mr. Chairman and committee members. My name is John Glover. I am the Vice President for Corporate Security at the Bristol-Myers Squibb Company. Bristol-Myers Squibb Company is a pharmaceutical and related healthcare

products company who's mission is to extend and enhance human life. The company does business in more than 100 countries around the world. I have been in this position for over 12 years. Before coming to Bristol-Myers Squibb, I spent 24 years in the FBI investigating federal crimes.

I was in charge of the FBI's Atlanta office when it conducted a major investigation into pharmaceutical sample abuse. The findings from this investigation were among the factors that led to the Congressional hearings that resulted in the enactment of the Prescription Drug Marketing Act. I have always believed that strict controls on the flow of prescription drugs are essential to protecting the health and safety of Americans. Concerns about the risk to public safety from adulterated and counterfeit imported medicines were paramount in the minds of legislators when they enacted the PDMA. In my opinion, concerns for the public health and safety of American citizens should continue to be paramount in the minds of this legislature, and should inform any legislation passed by this or any Congress.

The key points to my brief remarks today are as follows:

Counterfeiting of prescription drugs is a global problem.

Pharmacies, distributors, and criminal enterprise in Mexico are a significant source of the counterfeit and diverted medicines on U.S. shelves and in U.S. medicine cabinets.

Factories in India and China are the sources of most of the bulk active used in counterfeit pharmaceuticals worldwide.

Improved technology and the internet have contributed to the expansion of trade in counterfeit pharmaceuticals.

FDA, DEA, and U.S. Customs Service lack the resources to police effectively for counterfeit and diverted pharmaceuticals.

Counterfeiting of prescription drugs is a global problem.

Counterfeit pharmaceuticals are a global problem. The World Health Organization (W.H.O.) has estimated that between 5 and 8 percent of the worldwide trade in pharmaceuticals is counterfeit, and that the problem is worse in developing nations than in developed nations such as the United States. The W.H.O. acknowledges that 5 to 8 percent is only an estimate, since no one has conducted a systematic worldwide study of the counterfeit medicines problem. Nevertheless, based on my 24 years of experience with the FBI and my 12 years with Bristol-Myers Squibb, I am confident that "5 to 8 percent" is, if anything, an underestimate.

Increasingly, the illicit pharmaceutical trade resembles the worldwide narcotics trade, where product is sourced in one country, formulated into tablets or capsules in another country, packaged in yet another country, and then transshipped through other countries to its final destination.

Numerous dramatic stories of deaths and illness caused by counterfeits and diverted medicines in various countries such as south and subSahara Africa, Asia, Europe, and Latin America have been reported in the media.

A recent example of this nefarious trade was described in Scrip—World Pharmaceutical News in July 2000. The article reported that Italian authorities had seized 240,000 packs of counterfeit drug products in Genoa and Milan, and that the products were worth more than \$1 million. The counterfeit products were from India and China, and were intended for human and animal use. Italian authorities arrested ten individuals involved in this organized criminal enterprise.

Separate and apart from news reports, over the past several years, the pharmaceutical industry has been involved in various studies and investigations regarding counterfeit medicines.

A pharmaceutical security industry group conducted a 15-month study in the Philippines during 1994 and 1995. During this period, we collected 1,359 samples from 473 drugstores. We determined that 8 percent of the samples were counterfeit and that 11 percent of the drugstores visited were dealing in counterfeit medicines. Fully 17 percent of the medicines obtained were illegally imported or illegally diverted into the Philippines. The counterfeit medicines included cardiovascular, rheumatoid arthritis, osteoarthritis, asthma, anti-infective and anti-inflammatory drugs.

In a similar study in Indonesia, we collected 1,309 drug samples. While the results were not as conclusive as the Philippines study, one company reported a significant counterfeit problem with one of their best selling drugs and a lesser problem with another.

The pharmaceutical security group subsequently conducted a study in China. We collected 842 drug samples from 262 outlets in 11 cities. Five different counterfeits of the same products were found. During this same period, we encountered one state-owned pharmaceutical company that counterfeited three best-selling drugs from three different manufacturers and shipped these products to the Philippines

and to Europe. Counterfeiting in china has expanded in scope and sophistication since that time.

Pharmacies and distributors in Mexico are a significant source of dangerous counterfeit and diverted medicines on U.S. shelves and in U.S. medicine cabinets.

The pharmaceutical security institute is a security group representing the pharmaceutical industry whose primary focus is addressing the trade in counterfeit medicines. In a 1998 trip to Tijuana, a Pharmaceutical Security Institute representative visiting a pharmacy was steered to products which were said to be as "good as the originals but at lower prices." The packaging would have looked familiar to a U.S. customer—the labels were in English and the bottles appeared to be American. Nevertheless, there were significant differences between these Mexican knock-offs and legitimate U.S. products. First, there was no guarantee of the quality of the Mexican knock-offs. There was no way to know whether they had been manufactured in accordance with good manufacturing principles, or to know the conditions under which they had been packaged, stored, handled, or shipped. Indeed, there would have been no way for a consumer to know the true contents of the bottles. Mexican knock-offs could contain the proper active ingredient in the wrong amount, or they could contain a totally different active ingredient than the one listed on the label. The pills could be superpotent, subpotent, or even toxic. Second, it is often impossible for a consumer suffering from an adverse reaction to identify and contact the manufacturer of one of these Mexican knock-off drugs. The investigator in question was unable to locate one manufacturer, even when he described an emergency situation. Unfortunately, there was no company address or phone number on the label. After several calls, the distributor of the product was located, but on three successive days, he refused to provide a location of the manufacturer even when it was mentioned that someone was injured by their product.

In August of last year, investigators made another visit to Tijuana. Again the store clerk—who was not the pharmacist—directed the investigators away from name-brand products to what he called "generics." These products should not be confused with "generic drugs" in the sense that you and I understand the phrase. In the United States, when a drug loses its patent protection, the Federal Food, Drug, and Cosmetic Act permits generic manufacturers to market "generic" versions of the drug, subject to certain conditions. These U.S. generic pharmaceuticals must be identical to the name brand products on which they are based. Also, the manufacturers are subject to good manufacturing practice regulations. So-called Mexican generics are not approved in the U.S. and may not be manufactured in compliance with U.S. good manufacturing practices. They are not true "generics"—they are fake products designed to fool U.S. citizens. In Tijuana last year, we found products with familiar-looking packaging, English labels, and U.S. bottles. Some of the labels on these medicines identified listed a non-existent U.S. company as the manufacturer.

Factories in India and China are the sources of most of the bulk active used in counterfeit pharmaceuticals.

With the increase in international trade, it has become increasingly difficult to trace the pedigree or lineage of any particular counterfeit drug product. As I stated earlier, a product may be sourced in one country, formulated into tablets or capsules in another, packaged in yet another, and then transshipped through other countries to its final destination.

Recently we have found that companies in India and China are heavily involved in manufacturing the counterfeit drugs that eventually make their way to the Mexican border and into the hands of U.S. consumers. In fact, we currently believe that some products are sourced in India, fraudulently labeled in the San Diego area, and then shipped into Mexico for sale to unsuspecting Americans. A 1997 customs seizure of more than \$60 million worth of misbranded and counterfeit pharmaceuticals that were destined for Tijuana drugstores tends to support this theory. The active ingredients appear to have originated from India.

Also, in numerous instances we have found bulk active that was sourced in India, shipped to various European countries, and then shipped to Mexico. The documentation provided with these products indicated fraudulently that the product was sourced in Europe rather than India.

Finally, there is substantial consolidation in the border trade. During the PSI visit to Tijuana in September 1998, it was estimated that there were approximately 800 pharmacies operating in the Tijuana area alone. In August of last year, the number of pharmacies operating in the border area around Tijuana had been reduced to less than 100. Information has been received from reliable confidential sources that Mexican organized criminal elements are involved in the distribution and sale of counterfeit medicines in Mexico.

China is another significant source of the bulk active used in counterfeit pharmaceuticals. We have found counterfeit pharmaceuticals sourced from China all over the world.

Improved technology and the Internet have contributed to the expansion of trade in counterfeit pharmaceuticals.

As web-based pharmacies proliferate on the Internet, so does web-based counterfeiting. This is borne out by increased U.S. Customs seizures over the past few years.

One dramatic example of web-based counterfeit was described by the New York Times in March 2000. The U.S. Customs Service, along with Thai authorities, conducted searches of online pharmacies based in Thailand. Several arrests were subsequently made in Thailand along with six individuals in Albany, New York. Officials seized 20 computers, 245 packages ready to be shipped, and over 2.5 million doses of drugs. These counterfeit medicines are manufactured in unclean, nonsterile sites, which certainly would not meet FDA approval.

FDA, DEA, and U.S. Customs Service lack the resources to police effectively for counterfeit and diverted pharmaceuticals.

Improved packaging technology makes it difficult for even the expert eye to differentiate between manufactured labeled product and counterfeit labeled product. Certainly it is expecting too much to expect a U.S. Customs inspector to make this judgment. Further, limited resources affect the number of shipments that can be inspected at our ports and borders by U.S. Customs inspectors. FDA and DEA have similar resource constraints.

Conclusion

What can we and should we be doing to ensure that the world problem in counterfeit and diverted pharmaceuticals does not become a significant U.S. problem?

We must recognize that the U.S., as the largest and most lucrative market in the world, is the ultimate target of many counterfeiters and diverters. We must not make it any easier for criminal counterfeit operations than we already have.

Therefore, we must continue to:

1. Maintain our political will and not allow the desire for low cost medicines to undermine our commitment to protecting the public health of U.S. citizens.
2. Ensure that we maintain comprehensive legislation to protect our pharmaceutical industry and encourage innovation.
3. Aggressively enforce the laws designed to combat trade in spurious medicines.
4. Maintain strong penal sanctions against individuals convicted of violating the various drug laws.

Mr. Chairman and committee members, thank you for the opportunity to express my views on this important subject.

Mr. GREENWOOD. Thank you very much, Dr. Glover, for that testimony.

The Chair at this time would recognize James Christian, Vice President and Head of Global Corporate Security, Novartis International. You're recognized for 5 minutes.

TESTIMONY OF JAMES CHRISTIAN

Mr. CHRISTIAN. Mr. Chairman and members of the committee, my name is James Christian and as has been indicated I am Vice President of Global Corporate Security for Novartis. Prior to joining Novartis I spent 20 years with the United States Secret Service, the last 5 years as a Special Agent in Charge.

At Novartis, one of my responsibilities is to oversee the company's worldwide anti-counterfeiting operations. In the past 5 years, Novartis has participated with law enforcement and health authorities in over 100 counterfeiting investigations in 33 countries and involving hundreds of drug products. I have witnessed a considerable ingenuity and resourcefulness that unlawful enterprises utilize to manufacture and distribute ineffective and often unsafe counterfeit products. Drug counterfeiters present a severe and growing threat to the health and safety of U.S. citizens. Now is not

the time to weaken the country's defenses against such criminal activities. Novartis has a compelling interest in protecting the medicines that it currently markets as well as those under development. This year alone, Novartis will spend more than \$2.4 billion on research and development. More importantly, patients using Novartis' products must have every confidence that the drugs are safe and effective.

Counterfeit drugs are fake medicines, produced and packaged to look like the genuine article. They include products containing correct ingredients, incorrect ingredients, no active ingredient, an insufficient quantity of active ingredient or too great a quantity of active ingredient and usually have phony packaging and labeling. Counterfeiters are able to produce labels that are virtually indistinguishable from the true labels. They can also make and stamp tablets with company logos and put them in blister packs. We have scores of examples of counterfeit expired and adulterated medicines. One quick example that I'll show now is a product that is developed and we've seized in Colombia. This is the raw material used to make the tablets. This raw material is made up of boric acid, floor wax and leaded highway yellow paint. From this they go to the tablets and from the tablets they go to the blister pack and the labeling. I have a number of other examples on the table and a bagful of examples if committee members are interested later in the program.

Production of counterfeit medicines is pervasive outside the United States and is growing at an alarming rate. My written testimony contains detailed information about the extent of counterfeit activity in Latin America and Asia. As a result of a fairly recent investigation in Argentina, for example, 72 individuals were arrested, 7 tons of counterfeit pharmaceuticals were seized, 49 different counterfeit drugs were identified and 13 clandestine labs were dismantled and 5 print shops seized. In Colombia last year, more than 400 expired, adulterated or diverted or counterfeit products from 80 different pharmaceutical companies were seized by INVIMA, the Colombian food and drug authority. Pharmaceutical companies and law enforcement authorities have a difficult time controlling international counterfeiting practices. Many counterfeit pharmaceuticals are manufactured so cleverly that it is virtually impossible for consumers, government officials, law enforcement agencies, Customs officials to identify them as counterfeit. Detection is made more difficult by the practice now of mingling counterfeit, adulterated, expired, stolen and genuine product. When this occurs random or sampling testing is totally ineffective. Counterfeiters do not care about the quality and safety of the product. The goal is to sell a fake drug to an unsuspecting patient.

The United States cannot rely on foreign countries to enforce their counterfeiting laws and regulations. Many governments lack the interest, resources and technological sophistication needed to address the problem. Counterfeit products present a severe safety risk to patients. They are deliberately fraudulently mislabeled with respect to their identity and source. Active ingredients, if present, are often in an incorrect amount. Frequently, there is no active ingredient at all, but a completely different ingredient. They might be manufactured in garages, basements or warehouses under hor-

rific conditions. I now have a videotape from Colombia that is very short, but it will give you an idea of what these clandestine labs that manufacture counterfeit money, counterfeit products look like.

[Video shown.]

Now as bad as that looks, the final product, the quality is almost impossible to tell from the genuine and certainly now by a Customs Inspector.

Criminal counterfeiting operations have become more aggressive, more sophisticated. The resulting danger to U.S. consumer is greater than ever before. Now is not the time to diminish the capacity of the United States to prevent counterfeiting drugs from reaching our shores. It is time to strengthen our commitment to keeping our medicines the best and safest in the world. To do this, additional resources and a much stronger mandate are necessary for organizations such as U.S. Customs and the Criminal Investigative Unit of the FDA. Their approach must be international in scope if we are to maintain the present level of integrity in the U.S. pharmaceutical system. If you go to Bogota, if you go to Bangkok, you will find the presence of the FBI, the Secret Service, the DEA. You will not find a Criminal Investigative Unit of the FDA and yet this has the potential to be a much bigger problem than the problems those agencies were addressing.

Thank you.

[The prepared statement of James Christian follows:]

PREPARED STATEMENT OF JAMES CHRISTIAN, VICE PRESIDENT AND HEAD OF GLOBAL CORPORATE SECURITY, NOVARTIS INTERNATIONAL AG

My name is James Christian and I am Vice President and Head of Global Corporate Security for Novartis International AG. Prior to joining Novartis, I was a Special Agent in Charge with the United States Secret Service where my responsibilities included suppression of counterfeiting of U.S. currency in Latin America. At Novartis, I oversee operations to protect the assets and reputation of Novartis in the 140 countries in which the company markets its products or in which the products or their raw ingredients are manufactured, packaged, stored, or shipped. In this capacity, I have witnessed firsthand the considerable ingenuity and resourcefulness that unlawful enterprises in foreign countries utilize to manufacture and distribute ineffective and often unsafe counterfeit products. There can be no question that foreign drug counterfeiters take full advantage of offshore mail-order pharmacies, the Internet, and visitors from other countries to market their goods. Furthermore, if the United States permits the reimportation of drugs as provided in legislation enacted last year, the financial rewards for drug counterfeiters will ensure that they make every effort to penetrate deeply the U.S. marketplace causing considerable harm to the health and safety of U.S. citizens.

I. BACKGROUND

Novartis Group is a multinational research-based healthcare business headquartered in Basel, Switzerland, with U.S. headquarters in New Jersey. We have more than 67,000 employees worldwide with over 15,000 in the United States. The company's product line includes 126 prescription drugs to treat or prevent conditions as varied as rheumatoid arthritis, schizophrenia, hypertension, Alzheimer's disease, high cholesterol, migraine headaches, epilepsy, cancer, and organ rejection in kidney, liver, and heart transplants. Several weeks ago the FDA approved our new orphan drug, Gleevec™, for chronic myeloid leukemia, which represents one of the most significant cancer treatment breakthroughs in many years. Novartis has a compelling interest in protecting the assets represented by the drugs that it currently has in the market as well as those now under development. In this year alone, Novartis will spend more than \$2.4 billion on drug research and development. More importantly, it is critical that patients using Novartis products have every confidence that the drugs are safe and effective. For these reasons, Novartis dedicates considerable manpower and financial resources to addressing drug counterfeiting on a global scale. Accordingly, Novartis works closely with law enforcement and health

authorities in numerous countries to investigate and suppress the counterfeiting of its products.

II. COUNTERFEITING

Counterfeit drugs are "fake" drugs, produced and packaged to look like the genuine article. Counterfeit drugs may include products containing correct ingredients, incorrect ingredients, no active ingredient, an insufficient quantity of active ingredient, and have phony packaging and labeling. Illicit operations may combine counterfeit product with adulterated or expired product, or on occasion, with some genuine product to make detection more difficult. Counterfeiters employ state-of-the-art technologies such as desktop publishing to produce counterfeit labels that are indistinguishable from the true original labels. These labels put false "new" expiration dates on expired products and make adulterated or ineffective drugs look like the real thing. Counterfeiters have the ability to make and stamp tablets with company logos and even to package them in blister packs.

While we have scores of examples of such activities, there are some that demonstrate the deceit and danger inherent in drug counterfeiting:

- (1) A raid on a counterfeiter's facility uncovered tens of thousands of vials of a drug whose expiration date had long-since passed. The vials were soaked in hot water to remove the old labels, and counterfeit labels bearing a new expiration date were affixed. In similar circumstances, drugs in vials and ampules have lost their efficacy because their temperatures were raised to unacceptable levels during the label-removing process.
- (2) Our efforts also interdicted millions of yellow tablets that were virtually indistinguishable from the genuine product—including the company logo. These tablets were made of boric acid, floor wax, and lead-based yellow paint used for road markings. Sacks of these "raw materials" were stacked throughout the counterfeiter's site.

Counterfeiting is prevalent outside the United States and is growing at an alarming pace. A joint workshop of the World Health Organization and the International Federation of Pharmaceutical Manufacturers Associations concluded in 1992 that in some countries as much as 60 percent of all drugs may be counterfeit. Since then, every major pharmaceutical company has seen an increase in the volume of counterfeit medicines. Over the last five years, Novartis has assisted or otherwise been involved in over 100 investigations of counterfeiting operations, in over 33 countries, involving more than 11 Novartis products and more than 200 products manufactured by other companies.

A survey of the international media demonstrates that the problem of counterfeit, substandard, contaminated, and poisoned drugs is worldwide—fake Xenical in Hong Kong, phony ampicillin and AZT in Vietnam, counterfeit Mefloquine in Cambodia. Recently in the United States, counterfeit fertility drugs have been found in New York and phony Propecia and Viagra discovered in Boston. Counterfeiting and diversion are particularly prevalent and dangerous in Latin America and Asia.

Mexico and Central America. Counterfeit products are a major concern in Mexico, Central America, and the Dominican Republic. Counterfeiting in Mexico is particularly dangerous for American consumers because of the shared border between Mexico and the United States. U.S. consumers traveling over the border to Mexico to buy products off pharmacy shelves may purchase dangerous counterfeit or adulterated products. A recent article in the *New York Times* reported that a chemical analysis had found several sampled Mexican drugs to be counterfeit—including an anti-depressant, an ulcer treatment, and a diabetes medication. American law enforcement officials opined that the amount of counterfeit and substandard medications in Mexico could be as high as 25 percent. Based on our knowledge, the problem could be much larger. Moreover, in my experience, U.S. Customs and FDA lack the resources and infrastructure to police the border adequately to prevent criminal smuggling of bulk counterfeits from Mexico to the U.S.

Argentina. From May 1999 until June 2000, Novartis worked with authorities in Argentina to combat the counterfeiting of four Novartis products—Voltaren (an anti-inflammatory), Tegretol (an anti-epileptic), Hydergine (dementia), and Reliveran (arthritis). As a result of that investigation, 72 individuals were arrested, 7 tons of counterfeit pharmaceuticals were seized, 49 different counterfeit pharmaceuticals were identified, 13 clandestine labs were dismantled, and 5 print shops were seized.

Brazil. In early 1999, it became apparent to the pharmaceutical industry that there was a major counterfeit pharmaceutical problem in Brazil. At that time, 132 counterfeit products—from most major companies—were identified as being distributed in Brazil. The Pharmaceutical Security Institute (an industry organization formed to support anti-counterfeiting efforts) working with the Brazilian Minister

of Health trained a team of 25 investigators to attack the counterfeit medicine problem. Approximately 20 clandestine labs were seized and numerous arrests were made.

Colombia. Counterfeit drugs are manufactured in Colombia for international distribution. In 2000 alone, more than 400 products from 80 companies, either expired, adulterated, diverted or counterfeit, were seized by INVIMA (the Colombian food and drug authority) working with Novartis and other multinational pharmaceutical companies. Investigations, raids, and seizures are continuing with extraordinary results. So far, approximately 6 million ampules of counterfeit Voltaren have been seized. Tens of millions of counterfeit tablets of another pharmaceutical company's non-steroidal anti-inflammatory drug have been seized. Dr. Miguel Rueda, Director of INVIMA, believes that the counterfeit, expired, and altered drugs were to be distributed not only in Colombia but also in Ecuador, Peru, Venezuela, and Central America. While INVIMA is working hard to combat the problem in Colombia, the necessary resources are not always available.

Asia. The counterfeiting of pharmaceuticals is a burgeoning problem in China. For example, in March 2001, Novartis and other pharmaceutical companies participated in a raid with authorities in Shantou that resulted in the seizure of over 1800 cartons of counterfeit pharmaceutical products from 14 multinational companies.

India. Another threat to U.S. consumers relates to the distribution of bulk pharmaceutical products from India. India refuses to recognize intellectual property rights and as a result, through process patents, Indian companies manufacture and ship patent-protected bulk pharmaceutical products around the world. Technically, the Indian products should only be shipped to countries that recognize process patents, but in fact much of this bulk product shows up in countries that recognize product patents. In fact, there is reason to believe that some of this material is shipped to the United States for manufacturing and packaging, and then exported to other places such as Mexico. Often the product ends up back in the United States when American citizens go to Mexico to purchase pharmaceuticals. Health authorities in a number of Latin American countries believe that India and Cuba use the region as a dumping ground for batches of pharmaceuticals that are substandard. For example, health authorities have discovered products without sufficient active ingredient and contaminated with foreign materials including pieces of glass. Those products can be sold to U.S. consumers in Mexico or may be smuggled into the U.S. and placed on U.S. pharmacy shelves.

III. LACK OF CONTROL OF COUNTERFEITING

Novartis, like other drug companies, and, unfortunately, law enforcement authorities are hampered in the effort to control international counterfeiting practices by several factors including: (1) the difficulty of detecting counterfeits; (2) the lack of dedicated resources in local jurisdictions and the failure to give appropriate priority to anti-counterfeiting activity; (3) the ingenuity of counterfeiters and the ease with which criminal elements can resume operations at new sites; and (4) the lack of applicable criminal statutes and the prevalence traditionally light sentences.

Inability to detect. Many counterfeit pharmaceuticals are manufactured so cleverly that it is virtually impossible for consumers, government officials, and law enforcement agencies to identify them as counterfeit. Counterfeiters do not care about the quality and safety of the product. They concentrate their resources on the appearance of the product and its packaging. The goal is to sell a cheap, fake product to an unsuspecting consumer, not to provide a safe and effective medicine to a patient. It can be virtually impossible for consumers to tell the difference between a counterfeit and a genuine product. Even pharmacists, doctors, and government regulators can be fooled. Field tests can determine whether the active ingredient is present, but not whether the active ingredient is present in the appropriate amount, whether there are any impurities or foreign substances in the product, or whether the product is expired.

The ability to detect counterfeit products is made more difficult by the practice of combining counterfeit product, adulterated product, expired product, and genuine product. Distributors supply the resulting intermingled combination to physicians, hospitals, pharmacies, and health agencies. Such shipment might be 50 percent "bad." If a test is performed on a genuine pill from the intermingled shipment, the counterfeit shipment passes undetected.

Lack of enforcement. Many countries fail to enforce their counterfeiting laws vigorously. Local jurisdictions frequently lack the resources and technological sophistication needed to address the problem. Some countries spend their resources on other national priorities and not anti-counterfeiting activities. In other countries, criminal

operations have infiltrated the law enforcement and regulatory community, precluding effective enforcement of the law.

Professional criminal element. Drug counterfeiters may be extremely large, sophisticated and well financed operations or, at the other extreme, they may be small opportunistic enterprises. In Mexico, for example, it is believed that most, if not all, of the pharmacies located along the border, are owned and operated by Mexican organized crime groups. In Latin America, crime syndicates bring together manufacturing and printing skills and often link them with existing pharmaceutical distributors. By the time a counterfeiting operation is identified by a pharmaceutical company, it has generally been in operation for some time. The subsequent investigation to develop facts, identify suspects, and determine the locations of clandestine labs and print shops can take years. During that time counterfeit drugs continue to be produced. Oftentimes the company's investigation must be fully developed before the local government will take any official interest in the problem. Clandestine labs are usually crude and can be easily shut down and reopened elsewhere by counterfeiters who suspect that they or the location have been compromised. In my experience, the professional criminals who engage in counterfeiting of pharmaceuticals are able to elude arrest and prosecution by shifting their operations from location to location and by taking advantage of delays in the investigation process.

IV. THE THREAT TO U.S. CONSUMERS

There is ample opportunity for counterfeit products to enter the United States across the Mexican border. A recent survey by the Drug Enforcement Administration and U.S. Customs at the border between Tijuana and San Diego revealed that a sample group of 200 travelers returned to the United States with 28,409 dosage units. Assuming that 25 percent of Mexican pharmaceuticals are counterfeit or adulterated, those 200 patients alone may have brought 7000 counterfeit or adulterated doses into the United States.

Counterfeit products present a severe safety risk to consumers. Counterfeit products are deliberately and fraudulently mislabeled with respect to their identity and their source. They might be manufactured in garages, basements, and warehouses. The manufacturers do not adhere to good manufacturing practices. There is no guarantee the products were manufactured in a sterile environment, and no information about how the products were packaged, stored, handled, or shipped. Active ingredients, when present, are often in an incorrect amount. Often there is no active ingredient at all, or a completely different ingredient. If the medication is intended for a serious condition, an unexpected change in the dosage, the substitution of an illegal ingredient, or the lack of an active ingredient could well be life threatening. If the medication is intended for a serious and chronic condition, a month's supply of counterfeit drugs could place the consumer's long-term health in jeopardy.

Additional problems arise with expired and adulterated medicines. Parallel trade and diversion of medicines often results in labels being changed so that they are in the local language. There are instances where the products lose efficacy during the label change process. Labels are often added to outdated products, giving the appearance that the shelf life is much longer.

V. CONCLUSION

In 1987, the House Energy and Commerce Committee concluded that permitting re-importation of American drugs "prevents effective control or even routine knowledge of the true sources of merchandise in a significant number of cases." As a result, "pharmaceuticals which have been mislabeled, misbranded, improperly stored or shipped, have exceeded their expiration dates, or are bald counterfeits, are injected into the national distribution system for ultimate sale to consumers." Indeed, "the very existence of the market for reimported goods provides the perfect cover for foreign counterfeits." Since 1986, criminal counterfeiting operations have become more numerous, more sophisticated, and more aggressive. The resulting danger to U.S. consumers is greater than ever before. Now is not the time to weaken the ability of the United States to prevent counterfeit drugs from reaching U.S. citizens. If reimportation of prescription drugs resumes, Congress will soon be holding hearings to determine how to stop the flow of dangerous counterfeit medicines into the United States.

Mr. GREENWOOD. Thank you, Mr. Christian.

At this time, the Chair would recognize William Trundley, the Vice President of Corporate Security Investigations, GlaxoSmith Kline.

TESTIMONY OF WILLIAM TRUNDLEY

Mr. TRUNDLEY. Mr. Chairman, members of the committee, thank you for inviting me to testify today. My name is Bill Trundley, I'm the Vice President of Global Corporate Security and Investigations for GlaxoSmithKline and I'm based in London. I have responsibility for investigating counterfeit crime against the company and its customers worldwide. Prior to joining GlaxoSmithKline I was the head of Security for the Bank of England with additional responsibility for the secure production, storage and distribution of the Euro banknote including introducing anticounterfeiting measures. Prior to that, Mr. Chairman and members, I was in the British Army for 24 years with the Special Investigation Branch with responsibility for the conduct of some anti-terrorist and intelligence operations.

I intend now to make a short presentation to demonstrate the widespread incidents of counterfeit product within the global marketplace. As you can see, it's almost impossible for the consumer to tell the difference between genuine and counterfeit products. Look at the silver foils and the blister packs to see just how far the counterfeiters will go to copy the real thing. This particular counterfeit product was manufactured in Taiwan in sufficient quantity to supply the local market for 3 months. It's easy for the counterfeiters to copy batch codes or make their own packaging. Furthermore, there is simply no guarantee that reimported medicines are genuine or if they are genuine while out of the country they have been stored under the appropriate conditions.

This particular product is an antibiotic and was found on the market in South America. The product is designed to be used intravenously as well as in suspension in tablet form. This counterfeit version has no active ingredient.

This product is used exclusively for the treatment of HIV. The product was found to be totally ineffective. It was on the marketplace in Hong Kong. Criminals will exploit loose controls to introduce similar counterfeit medicines into the U.S. marketplace. The net result will be to put the lives of patients at risk. The taxpayer or the purchaser of the medicines becomes the victims of wholesale fraud if they're duped into using products that have been switched for the counterfeits.

Dermavaid creme is used to treat skin complaints. this product found its way on to the U.K. market from India, despite strict EU importation laws. On analysis, it was found to be dangerous for use on the human skin. And I have to say that by relaxing its import conditions, the U.S. is making itself more vulnerable to this sort of practice.

The package on the right is counterfeit, but can anybody here tell the difference easily? This slide relates to a case that is only 3 months old, so please don't think it's an old problem that no longer exists. This product is used for reducing pain and was found on the market in the Far East and in Sub-Saharan Africa. One other point, I should make is that if a product is potentially harmful, it may be impossible to conduct proper recall as the audit trail will be all but lost once the product has been sent abroad. One example of a fatally harmful product is the case in 1994 which members may be aware of when over 200 children in French Niger died as a result of being vaccinated with what later transpired to be con-

taminated river water. This was during a government-sponsored vaccination program.

This particular product is used to treat acne. Personally, I would not allow my teenage children to rub this counterfeit product into their face. This was discovered in the Philippines and you can see from the quality of the packaging the lengths to which the counterfeiters will go to.

This product is used for the treatment of asthma in children and as you can see it was discovered in Brazil 23 years ago. The counterfeit version has no active ingredient.

Now please compare and contrast this appalling trade with the companies that each invest billions of dollars every year in research and development to ensure the safety and efficacy of the product where the products are manufactured in sterile conditions and to high standards of GMP and GLP. And the ethical producers are subjected to continual testing and quality control to ensure the safety and efficacy by both in-house and the Federal authorities.

This is in marked contrast to criminal operations. This slide shows how the counterfeit Zantac was manufactured in Taiwan. The conditions are quite appalling.

This is a slide that shows how the counterfeit Panidol was made. As you can see, the product was made in sweatshop conditions and the circumstances that are wholly unacceptable.

This final slide shows the dreadful conditions in which counterfeit medicines are mass produced and stored. The photograph was taken during a raid on premises in Manila that resulted in the discovery of the counterfeit acne cream. I would like to emphasize, Mr. Chairman and members of the committee that despite having strong controls in the European market, counterfeit products still find their way on to the marketplace. The United States represents 40 percent of the global pharmaceutical market. It is therefore the most attractive and lucrative market and one which the counterfeiters would naturally turn to.

Counterfeit product is made in primitive, dirty and dangerous conditions, often exploiting cheap, unskilled, local labor. At best, counterfeits do not contain active ingredients. At worst, they can be positively harmful and fatal.

Finally, more often now, medicines are sold direct to the customers through the Internet or mail order. This makes it even more difficult for them and the authorities to know whether or not the product they're using is safe.

Mr. Chairman, members of the committee, thank you very much.
[The prepared statement of William Trundley follows:]

PREPARED STATEMENT OF WILLIAM TRUNDLEY, VICE PRESIDENT, CORPORATE
SECURITY AND INVESTIGATIONS, GLAXOSMITHKLINE

Mr. Chairman, members of the Committee, I am Bill Trundley, Vice President of Corporate Security and Investigations, at GlaxoSmithKline which is a research-based pharmaceutical firm. The company has US headquarters, research and development, and manufacturing facilities in both North Carolina and Pennsylvania. GlaxoSmithKline employs over 20,000 personnel in the United States and 90,000 elsewhere around the world.

The purpose of this testimony to your subcommittee is to briefly discuss some of the Company's experience with those who produce counterfeits of our medicines, and to give you some perspective on the scope of this problem. The issues are with public safety because: there can be no guarantee that re-imported medicines have been

stored under the correct conditions to ensure their efficacy; the audit trail will be all but lost once the product has left the country, making it almost impossible to guarantee a successful recall of the product if this becomes necessary; and criminals will exploit any perceived loosening of controls to place counterfeit product into the US legitimate market.

First, as to scale, the World Customs Organization has estimated that "around 5% of all world trade may be falsified, and in view of the relative ease with which pharmaceutical products can be counterfeited and transported, there is little reason to expect a lower figure for such products." Current estimates of the cost of counterfeit medicines range from 6 to 12 billion dollars each year.

Counterfeiting is most prevalent in developing countries, but there is always the risk that these products could find their way into almost any country. Former FDA Commissioner Jane E. Henney has said that she and her Canadian counterpart are concerned that, if imports were allowed, the U.S. demand for drugs from Canada could cause Canada, and I quote, "to somehow be used as a front for counterfeit or contaminated products...one has to be concerned about safety issues here." End quote.

While the size of counterfeiting operations can vary from a small back-room unit to a larger factory-like facility, the one common thread is the complete lack of regard the counterfeiters have for the regulatory and quality control framework that exists for the manufacture of ethical pharmaceuticals.

Their formulations and raw materials have not been tested in clinical trials, monitored for adverse reactions nor proven to meet the label claims of efficacy or stability throughout the claimed shelf life. They may use cheap substitutes for active ingredients, the wrong active, or even no active at all. Their processes and equipment are not validated, and they probably operate without any monitoring of product specifications. False documentation is used to help introduce the sub-standard goods into the legitimate distribution chain.

Unfortunately, however, it is relatively simple to produce a counterfeit that, on the surface, looks remarkably similar to the genuine article.

Counterfeit medicines are also a cynical exploitation of the trust patients place in pharmacists and other health care providers. The counterfeiters rely on the reputation and good name of prescribers, manufacturers and their products in order to defraud, and possibly harm, an unsuspecting and vulnerable public. The most troubling aspect of this crime is its negative impact on the lives and well being of patients. The net result is to put the lives of patients at risk, as they may unwittingly be sold counterfeit or sub-standard medicines as part of life-saving treatment or for pain relief. Patients may then lose confidence in the product and in the medical profession as a whole, causing them to stop their particular course of treatment. The taxpayer will become the victims of fraud if they are sold products that have been switched for counterfeits or for sub-standard medicines. This will result in serious harm to legitimate business such as the manufacturers, the distributors and the retail pharmacies.

Let me quote a few examples:

- In Ghana, ten percent of all hospital deaths are due to fake or subpotent medicines.
- In 1996, hundreds of Nigerians either died or suffered permanent brain damage from a counterfeit version of a meningitis vaccine.
- In 1997, fake medicine killed 88 children in Haiti.
- 223 children died in Bangladesh over a two-year period after taking fake anti-malarial pills.
- One study showed that only one quarter of all medicines bought from street vendors in Nigeria were genuine.

Let me leave you with the thought that, while the counterfeit products look similar to real medicines, the operations that produce counterfeit medicines bear little or no relation to the facilities required to produce genuine medicines. I believe the scale will increase in a very short period of time, particularly when internet and mail order selling becomes more widespread as there will be even less opportunity for the customer to be sure that it has been purchased from a trustworthy source.

Our manufacturing facilities and standards are complex and rigorous. Our whole operation is subject to rigorous control and inspection both inhouse and by the Federal Authorities to ensure the safety and efficacy of the product. The counterfeit operations, on the other hand, are not. This is indeed a case where one cannot judge a book (or a medicine) by its cover.

Thank you for allowing me to testify on this important topic. I will be happy to answer any questions you may have relating to our interest in this issue.

Mr. GREENWOOD. Thank you, Mr. Trundley for your testimony. We appreciate it.

Mr. Haislip for 5 minutes.

TESTIMONY OF GENE R. HAISLIP

Mr. HAISLIP. Good afternoon, Mr. Chairman, distinguished members of the committee, my name is Gene R. Haislip and I'm a consultant to the pharmaceutical and chemical industry.

Mr. GREENWOOD. Mr. Haislip, let me interrupt you. Is your microphone turned on? Just pull it a little closer and speak into the silver one, not the black one.

Mr. HAISLIP. Sorry. Thank you. I'll start again. Good afternoon, Mr. Chairman, distinguished members of the committee, my name is Gene R. Haislip and I'm a consultant to the pharmaceutical and chemical industry in the area of controlled substances and chemicals which, as you've heard this morning, are frequently diverted from legitimate channels into the illicit drug traffic. Prior to that I served most of my career in the Drug Enforcement Administration and during the last 17 years of my service I was the head of the Office of Diversion Control which is the office in DEA that has responsibility for all the programs, investigations and activities dealing with that subject and I'm very pleased to have this opportunity to address you on I think what we all see as an extremely important and sensitive area and a growing problem and that is the problem of counterfeit pharmaceuticals.

I have submitted a lengthy statement for the record and with your permission I'll just proceed to summarize some of the main points and then answer such questions as you may have.

Well, counterfeiting controlled substances is not new. It's been going on for quite some time. And it's a very interesting and important problem and I have detailed some of the extraordinary experiences we have with that in my testimony. One of the situations that I mention is very unique, I think, because it was a case in which at its height really most of the factories that produced this particular drug it was called quaaludes in those days, most of the factories in the world producing that particular drug were really just producing it for the illicit drug traffickers. They were virtually the only real customers for that commodity. Very little of it was being sold to any legitimate enterprise. And in addition to that, of course, they were counterfeiting a product that was available in the United States, but at that time the legitimate product had only become about 5 percent of the total quantity of that drug which was available in the United States. In other words, about 95 percent of it was the counterfeit product that had been smuggled into the country from Colombia where it had been counterfeited. And so I think that that case is interesting to me because it shows just how far things can go.

Well now we see that in addition to this historical counterfeiting of controlled substances, there's a growing problem of counterfeiting of general pharmaceuticals of all varieties and for virtually all medical purposes and like the counterfeiting of controlled substances, it too is almost exclusively an international problem. That is to say, it's a problem that probably could not exist in the serious dimensions that we're experiencing without the benefit of global

commerce and what it can provide to criminal organizations and I'd like to just emphasize a few points about that, if I may.

Well, the first thing I'd like to point out is this is not really something that's very difficult to do. It's quite easy to obtain all the raw materials and all of the technology that you need to produce the products that you have seen in the various demonstrations this morning and a lot of times, I mean if you wish to, you can do this indirectly and retain your anonymity by simply using brokers in some of the major commercial cities of the world. It's the broker that finds the source of these materials and the source, the manufacturer, supplier, never knows who the customer is. The source is dealing with the broker and the broker is dealing with the customer and by the way for whatever reasons, depending upon what you're trying to do, if you need for those goods or that you've purchased to change identity or to change their source, this can be done for you too and it's customarily done in some of the great free trade zones of the world. These are special zones that you find particularly in the Caribbean and in Europe and also in parts of Asia. We don't really have that institution in the United States. Sometimes it's called that, but it's not really the same. Well, in those free trade zones, the goods that are being purchased in this case by criminal organizations come into the free trade zone. There is very little record keeping required and no inspection of these commodities because they're regarded by the country that they're entering as being just in transit. So it cannot possibly be a problem for them, whatever it is. They're simply there in transit.

But they're there in transit, you can take them into your own warehouse. You can rent space within a free trade zone because it's not something like this room here. It's more like a small city, usually behind a fence and there, you can do whatever you need to do. You can even do your counterfeiting there, but if you need to change the identity of those goods, or if you need to repackage them or relabel them you can do that there and they leave the free trade zone as something that did not—they were not, when they arrived. So as I've often said, things come into that free trade zone and they just disappear because they never come out the other end. Something else comes out the other end. So I think that's important to remember in terms of any idea of trying to control the source of much of this international commerce. And as far as production, well, I think you've seen some of the examples of some of the incredibly crude production that really dominates most of this activity, but sometimes it's quite sophisticated because we have cases in which criminal organizations have gone to parts of the world where for political and economic reasons, there's a lot of desperation and they can corrupt the factory management. In one case, in this particular case in Eastern Europe, a secret facility was established within the factory, just known to a few employees just to fill the orders of this particular criminal organization for the particular commodity they wanted and even went so far as to purchase one of the top of the line brand new German tableting machines that could produce 400,000 tablets an hour to install in this secret facility and if that's not something that's convenient, can't find the right factory to try to corrupt, then you can—some countries, you can rent a factory. You can go to India and places like

that, you can rent a factory for the weekend or maybe just for night time or a couple of weeks or whatever you want to do. All of the equipment is there, they really don't inquire as to what you're doing if you can pay the rent. So that's another option. And then we've seen in a number of cases an incredible thing of criminal organizations really establishing what amounted to their own little miniature pharmaceutical factory, buying brand new reaction vessels, the vats, drying apparatus, all the piping, ductwork, everything they needed in a secret facility, usually somewhere in the suburbs. This particular one was in a large European capital city.

Well, the second point that I'd like to make is that many of the examples I've given in my testimony concern controlled substances, but I want to make the point that in dealing with these problems in regard to controlled substances, difficult as it is, DEA and others do have some advantages. There is an international infrastructure which exists. There are three—

Mr. GREENWOOD. Mr. Haislip, I don't want to be rude, but we need you to summarize and we'll get back to you in questions.

Mr. HAISLIP. Thank you. I'll try to do that quickly. So there are some advantages in some of these cases, but in the case of general pharmaceuticals there is no international infrastructure that we can take advantage of. I'll just close by mentioning three points that I'd like for you to give some consideration to. The first is I think this problem has to grow and so we do really need to increase our law enforcement capability to deal with it. The second is I think there's a need to simplify our laws and make them more practical and workable because really in many cases now they're too baroque and they probably will not really work and last is, it's time to consider some kind of major diplomatic effort to create the kind of international infrastructure we do not have. I apologize for going over time. Thank you very much.

[The prepared statement of Gene R. Haislip follows:]

PREPARED STATEMENT OF GENE R. HAISLIP, CONSULTANT, CONTROLLED DRUGS AND CHEMICALS, LAW, POLICY, ADMINISTRATION AND ENFORCEMENT

Mr. Chairman and distinguished members of the Committee, my name is Gene R. Haislip and I am presently a consultant to the pharmaceutical and chemical industry on issues involving controlled drugs and chemicals. I served for 29 years of my government career in the US Drug Enforcement Administration and, for the last 17 years, was the head of the agency's Office of Diversion Control from which I retired as a Deputy Assistant Administrator of DEA in March of 1997. This is the office responsible for all of the control and enforcement programs dealing with legitimate drugs and chemicals that are diverted into the illicit drug traffic. I am also now assisting the United Nations Drug Control Program in the design and implementation of a chemical control program in the Central Asian Republics bordering Afghanistan.

I am very pleased to have this opportunity to testify before you today on a subject of great importance to our fellow citizens and one that has occupied so much of my professional effort. It is my sincere hope that I will be able to make some small contribution to your deliberations.

Drugs and pharmaceuticals have become a major and pervasive social concern both because of their life-giving benefits and, in many cases their debilitating abuse. It is crucial that we take measures to minimize these abuses and at the same time, seek to insure that our citizens can rely upon the efficacy, and purity of their medications. The extraordinary availability of technology, the speed and ease of global commerce and the ingenuity of the criminal mind have resulted in the massive diversion and illicit manufacture of drugs of abuse and have also begun to undermine the integrity of vital medicines by the trafficking in bogus, counterfeit products which may cause the death or injury of innocent, unsuspecting persons.

Much of what I will relate in my testimony deals with the problems of the diversion, clandestine manufacture and counterfeiting of that smaller group of pharmaceuticals known as controlled substances. However, the lessons of this experience are absolutely critical to understand the challenges that we face in dealing with all classes of pharmaceuticals. In most cases, the criminal technique employed for one, are essentially the same for the other, except that in the case of non-controlled products, we lack many of the basic tools with which to attack these problems. Hereafter, I will attempt to develop this in greater detail, but first, some basic statement of the situation is necessary to establish a context.

I. NATURE OF THE PROBLEM

The demand created by addicts and drug abusers is obviously of quite a different nature than that of legitimate consumers for the medicines they require. Yet there is a certain similarity which in both cases may result in stimulating the traffic in counterfeit pharmaceuticals. Although most people commonly think of the illicit drug traffic in terms of such drugs as heroin, marihuana or illicit cocaine, in fact, many important legitimate drugs are also powerful narcotics, stimulants or depressants that are frequently sought by drug abusers.

Just like other consumers, drug abusers and addicts have learned the various brand names and appearance of the drug products they are seeking. Consequently, drug traffickers employ every criminal means they can to obtain these legitimate products to sell to their customers at tremendously inflated prices. But because of controls, it often happens that these products cannot be obtained in sufficient quantity from legitimate sources and drug traffickers undertake to counterfeit their own dosage forms to meet the demand.

In a similar fashion, criminal organizations sometimes seek to meet the legitimate demand for brand name pharmaceuticals by counterfeiting inexpensive, perhaps entirely bogus dosage forms in order to defraud both legitimate patients and manufacturers. If the legal and law enforcement situation is inadequate to prevent such schemes, cheap, impure, ineffective and perhaps highly toxic counterfeits can drive out the legitimate product. This is the subject with which we are concerned in this hearing.

II. METHAQUALONE DIVERSION: A PROTOTYPIC EXAMPLE

I know of no finer example of the capabilities of international criminal groups to corrupt global commerce than the massive illicit traffic in counterfeit Methaqualone tablets known as "Quaaludes" which occurred in the early 1980s. It is for me, largely a personal story, but briefly worth the telling because it illustrates how far such a problem can develop. All of these same conditions continue to exist and generally characterize the traffic in all diverted and counterfeit pharmaceuticals.

During the late seventies, a strong depressant drug known as "Quaalude" became a major drug of abuse, especially among adolescents. This resulted in increasing addictions, overdose deaths, and an extraordinary rate of automobile fatalities. At the time, a US company was manufacturing about seven metric tons of the drug a year for legitimate medical use and much of it was being diverted. Suddenly, it had become a drug which was producing as many deaths and injuries as either heroin or cocaine.

By 1980, we had determined that the country was being inundated by these Quaalude pills in such extraordinary quantities as to far exceed national production. By reviewing the DEA daily enforcement reports, it soon came to my attention that shipments containing one and two tons of these pills were being seized almost weekly from small aircraft that had originated in Colombia. The tablets turned out to be counterfeits but were equally potent and usually contained the 300 milligrams of the drug just like the legitimate US product.

A quick check revealed that this synthetic drug was not manufactured in Colombia and I set off for Colombia, and particularly the port of Barranquilla, with the task of discovering the original source of this material. As a result, the Colombian Customs and National Police were soon making the seizures which permitted us to gradually piece together the entire story of this traffic and put an end to it. It is one of the very few complete victories of our enforcement efforts, in that this huge billion-dollar traffic was eliminated. Here is what we found.

The Colombian drug traffickers had identified every known source of the legitimate manufacture of this drug, which involved countries in Western Europe, Eastern Europe and Asia and brokers and free trade zones in many others. Through one technique or another, they were purchasing virtually the entire global production of bulk Methaqualone powder for eventual shipment to Colombia where it was rendered into counterfeit Quaalude tablets exactly like the popular legitimate product.

produced in the US. As a result of establishing the production capacities of these foreign facilities and the large seizures which we began to make, I estimated that approximately 150 metric tons of the bulk drug was being diverted and counterfeited each year. This was more than twenty times the quantity of the legitimate pills then being manufactured. In other words, the world's factories were mostly supplying only the drug traffic, and the legitimate product represented only about 5% of the total availability. Congress finally eliminated all manufacture of this drug in the US and it has also ceased to be manufactured globally.

III. DIVERSION TECHNIQUES

What is most instructive is the manner in which all of this was accomplished. There were essentially two ways in which the material was obtained from source manufacturers. The most common method was to place orders through brokers, usually operating in the great free trade zones such as Rotterdam or Hamburg, or in Switzerland. In this way, neither party knows the identity of the other and the shipment is protected from scrutiny by Customs authorities that routinely make no examination of goods in transit. These are considered harmless because they are not staying in the country and can do no harm to their temporary host! Moreover, if special labeling and shipping arrangements are desired in order to evade attention while in transit or upon arrival, it is easy to find a broker who will oblige. Essentially, the drugs enter the free trade zone and disappear from the face of the earth. The manufacturer may wonder who is ordering such quantities of drugs but has no legal responsibility to inquire.

The other method of obtaining the drug was to deal directly with the manufacturer. In one case, traffickers sent representatives to a foreign factory with suitcases full of US dollars to negotiate for multi-ton shipments. Their attempt to corrupt the management at this factory—which was partly owned by the foreign national government—was successful. As will be seen, similar, and even more blatant situations of the absolute corruption of factory management have arisen.

IV. CLANDESTINE PRODUCTION AND COUNTERFEITING

In the case of Methaqualone, all of the active pharmaceutical ingredients (APIs) were purchased from legitimate sources and the actual counterfeiting occurred in Colombia. This is perhaps the easiest part of any clandestine operation. Used multi-stage tableting machines are readily available on the international market or they may be purchased new without arousing suspicion. It is also probably easy to substitute candy machines, which perform essentially the same functions as tableting machines. Counterfeiters are also quite capable of manufacturing capsules, ampoules, and blister packs. This is often seen on the Mexican border in the traffic in counterfeit steroids, while capsules have been used for counterfeit amphetamines (Black Beauties) beginning in the early seventies.

In the course of investigations of this type, it is quite common to find that persons with professional experience in the legitimate chemical and pharmaceutical industry have been recruited to perform the technical functions for which they were trained. On occasion, these individuals will in fact contact former colleagues still employed in legitimate enterprises and who are usually innocent of the purpose, to obtain sources or supplies.

If the desired bulk material (APIs) can not be purchased, arrangements can be made for its production. This is more likely to occur in those situations where legitimate facilities are experiencing financial difficulties, such as in Eastern Europe or in developing countries. In one such case, arrangements were made with the director and chief chemist of a struggling East European factory to establish a secret production facility within the company's 17-acre campus. It was easy to obtain the necessary chemicals without arousing suspicion and to relocate production equipment. To complete the arrangement, a new, top-of-the-line tableting machine which could produce 400,000 tablets per hour was purchased from a German firm. In another case, in a neighboring country, it happened that this factory was a producer of an important precursor material and some of the management and personnel decided to use it to establish an illicit production facility within the company. Unfortunately, as a result of political upheavals and marginal economies, there are many such situations like these, which are often ripe for corruption.

If it is not possible to corrupt the management of a suitable facility, in some countries a criminal organization may rent an existing facility during evenings or for weeks or weekends. But it may be more expedient to build your own facility. There are examples in both Western and Eastern Europe in which this has been done for drugs such as MDMA and Methamphetamine. In these cases, very knowledgeable, well-funded criminal organizations acquired a suitable site in the city or the suburbs

and proceeded to purchase brand new, top-of-the-line reaction vessels, tableting machines and vats and piping and dryers. These were small but modern, up-to-date, elegant production facilities costing more than a million dollars. In one of the more fascinating cases, a group of traffickers purchased large lots of cocaine in Colombia for distribution in Europe to finance their secret factory in a European capital. This factory was intended to supply illicit markets in both Europe and the US.

V. PACKAGING AND DISTRIBUTION

Counterfeit packaging is generally no more difficult than counterfeiting tablets. In most cases, only the original legal manufacturer of the real product can tell the difference, and then only on close examination and search of records.

Distribution is probably the most difficult and risky activity of pharmaceutical counterfeiters. If the product is destined for the illicit drug traffic, it involves all of the risk attendant to the smuggling of heroin or cocaine. If the product were intended for legitimate consumption, the task would be much easier. The product itself appears to be legitimate and would cross Customs barriers with less notice and suspicion, especially since the services are focused on illicit drugs and commodities which require so much of their effort. Certainly, it is easy to establish a "front company" with four or five employees to receive and market the goods to legitimate distributors. Such "companies" have been routinely used in the US to import precursor chemicals for distribution to illicit manufacturers of Methamphetamine. Of course, the ease with which this can be accomplished will depend on the strength and enforcement of national legislation.

VI. DIVERSITY OF COUNTERFEIT PHARMACEUTICALS

A. *Drugs of Abuse*

In the examples above, I have dealt primarily with the controlled pharmaceuticals that concern DEA. Before turning to other areas, I should like to complete this picture with a very brief summary, as the example given is only remarkable because of its scope and effect upon the US.

In the early 1970s, large quantities of secobarbital and amphetamine were imported into Mexico for the clandestine production of counterfeit capsules for illicit distribution in the US. These capsules closely resembled the products that had been previously obtained by traffickers from the Mexican subsidiary of a US firm. When their source of supply was cut off, they simply continued their illicit business with counterfeits. The same situation appears to have developed as a result of the control of steroids. When the diversion of these drugs was virtually eliminated by act of Congress in 1990, sophisticated counterfeit products immediately increased along the Mexican border.

In recent years, Europe, Africa, Asia, and the Middle East have all experienced similar large-scale diversion and counterfeiting of drugs of abuse. These include a variety of stimulant drugs ranging from amphetamine to Fenetylline, pemoline, amfepramone, and phentermine. It appears that both legitimate and clandestine manufacturing sources of bulk material have been used at various times. Clandestine laboratory and counterfeiting facilities producing such materials have frequently been seized in the Balkans and major points of sale and distribution are focused on Africa and the Middle East. Other commonly counterfeited products include Mandrax (the European form of methaqualone), Diazepam (Valium), Flunitrazepam (Rohypnol) and other benzodiazepines.

B. *General Pharmaceuticals*

The evidence suggests that the counterfeiting of other classes of pharmaceuticals is equally widespread. The first international effort to define the problem was a workshop organized by the World Health Organization (WHO) together with the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) in Geneva in April of 1992. It found that the counterfeiting of medicines had greatly increased and involved billions of dollars annually. A recent list of actual case reports from various countries included the following types of counterfeit medications: antibiotics, diuretics, antimigraines, antiparkinsonians, analgesics, antispasmodics, muscle relaxants, antianaemics, antihistamines, corticosteroids, antifungals, vasodilators, tranquilizers, vaccines, antimalarials, birth control pills and more. We may say that most of the classes of drugs that can be marketed to consumers were involved.

The WHO Department of Essential Drugs has continued this work and in 1999, issued a very commendable set of guidelines for the development of measures to combat the problem. This report took note of some of the increasingly common "horror stories" of the carnage caused by defective counterfeit products such as deaths

of children resulting from liver damage caused by the inclusion of toxic substances and unplanned pregnancies resulting from birth control pills containing no active ingredient.

The reason for their growing availability and popular acceptance, as noted by WHO executive Dr. Suzuki at the World Health Assembly in May 2000, is the combination of "profit and price", the usually dynamic of any drug traffic. Pharmaceutical counterfeiters, who do not have to trouble themselves with producing a quality product, or paying for any of the expensive research that originally created it, can concentrate on the authenticity of appearance and still offer a bargain price. A speaker from the Health Ministry in Benin observed that people were dying from counterfeit drugs daily, but continued to buy them because of their relatively cheap price. While visiting Nigeria some years ago, I found that the usual "pharmacy" services were offered on the street from the trunk of beat-up vehicles where, according to experts, most of the modern medicines were counterfeits.

WHO reports that although counterfeit pharmaceuticals are extremely common in developing countries, they have also been found in developed countries as well. Indeed, the principal consumer interest driving much of the counterfeit pharmaceutical market along the Mexican border is also the desire for cheaper medications. Who wants to pay more when you can pay less? Who wants to pay for another office visit to the doctor when you can buy the drug that you have been using at a cheaper price on the other side of the border, and without a prescription!

VII. DEFICIENCIES IN CONTROL AND ENFORCEMENT

Perhaps the greatest service that WHO has rendered is to enumerate the current massive deficiencies in national and international efforts to deal with the problem. I think that those of us who work in the area of controlled drugs are particularly aware of this because of the total lack of most of the tools, institutions and practices that we regularly use. I am perhaps especially sensitive to this, having so often experienced the frustrations of laboring to organize international enforcement cooperation in the absence of clear and specific legal authority. This proved to be an excruciating problem in dealing with the example I gave of Methaqualone which, although the subject of an extraordinary illicit traffic was not under legal control in most of the countries that were feeding it. The first attitude is always the same; "We don't have an obligation, we don't have the authority, and we don't have the time." Let's look at some of the specifics.

The counterfeiting of pharmaceuticals is a thoroughly international problem. Production and distribution seldom occurs within a single country and often involves global commerce. Yet there is no specific multilateral treaty imposing obligations to criminalize, report, or cooperate in the suppression of this traffic, nor any international staff to collect, analyze and disseminate information. This contrasts sharply with our work in the area of drugs of abuse where we have had treaties since 1911 and a Board and staff, which monitors their compliance.

Perhaps of most importance is the fact that, as a result of efforts that DEA and others have made, a functioning, effective informal international law enforcement effort has been constructed around these agreements. The staff of the International Narcotics Control Board is daily working with the law enforcement agencies of dozens of countries which all communicate and cooperate together in operations to suppress illicit diversion of both controlled drugs and chemicals. I assure you that the results are quite impressive and have had significant impact on the traffic in a long list of narcotics, stimulants, and depressants that are often diverted into the illicit traffic, as well as chemicals for the manufacture of methamphetamine, amphetamine, MDMA, cocaine, and heroin. This structure does not exist in the area of counterfeit pharmaceuticals.

Since there is no treaty, there are also no legal obligations to penalize certain actions, or designated agencies to systematically collect intelligence or assist each other in investigations. I would defer to the FDA for an account of the situation in the US, but in most cases, I doubt that there is specific assignment of clear enforcement responsibilities and mandate, together with dedicated personnel and resources. Usually, such laws as exist are of a regulatory nature and are generally the responsibility of the Health Ministries. The national law enforcement agency may help out on a selective, ad hoc basis. This approach is lacking in the advantages that we possess in the area of controlled drugs and chemicals. In short, on a global level:

- National laws are often inadequate,
- International shipments are not searched or verified in free trade zones,
- There is a lack of dedicated enforcement personnel and resources,
- There is no systematic data base and no requirement for one,

- There is no specific treaty or set of uniform international obligations,
- There is no dedicated staff to monitor compliance, and
- There is no functioning, systematic international law enforcement effort.

VIII. FUTURE CHALLENGE OF THE GLOBAL ECONOMY

The pharmaceutical industry has become an increasingly important part of health care and is deserving of specific attention, regulation and protection from crime and corruption. It is clear that there are strong financial incentives to engage in pharmaceutical counterfeiting. The level of criminal activity can be expected to increase rapidly with the globalization of commerce and the emphases on speeding this commerce through Customs barriers. Moreover, the increasing variety, effectiveness and elegance of pharmaceutical remedies will also increase these financial incentives.

The potential damage from this criminal activity is enormous and includes:

- Injury to patients whose maladies go untreated because of reliance upon substandard or entirely bogus counterfeit preparations,
- Injury to patients who unwittingly consume counterfeit preparations containing poisonous ingredients,
- Damage to the entire public health system by undermining public confidence in medications and the pharmaceutical delivery system,
- Damage to the pharmaceutical industry in terms of lawful revenues and public confidence, and
- Provision of additional financial support for crime, violence and corruption.

I think that in so far as the United States is concerned, we have thus far been spared most of the consequences of this problem, although there is ample warning on our southern border of what it will look like, if unattended. But to protect our people in the future, and to establish an enforcement regime that will protect all people, we must invent some things that do not now exist.

Thank you very much for your attention and for this opportunity to contribute to your valuable work.

Mr. GREENWOOD. We appreciate your testimony.

Mr. deKieffer.

TESTIMONY OF DONALD deKIEFFER

Mr. DEKIEFFER. Thank you very much, Mr. Chairman. Good afternoon to the committee. My name is Donald deKieffer and I'm an attorney here in Washington, DC. I've been practicing international trade law for around 30 years now. Previously, I was the General Counsel to the U.S. Trade Representative. In the last 15 years we've concentrated part of our practice on international antidiversion and anticounterfeiting. In that period, we've identified thousands of international counterfeiters and diverters, including hundreds of individuals and companies who are selling counterfeit and diverted drugs right now in the United States.

Today I considered dozens of different issues that are relevant to these hearings: intellectual property rights, R & D funding for the next generation of drugs, improvements in cooperation between various law enforcement agencies in the effective delivery of drugs to impoverished nations. But rather than address all those, each one of which might be the subject of a separate committee hearing, I'd like to talk about three things. The first is that permitting diverted drugs into the United States market will destroy the current regulatory regime. Second, the safety and efficacy of the U.S. drug supply will be placed in jeopardy. And third, permitting uncontrolled imports of prescription drugs will not significantly reduce costs to most consumers, but will enrich unscrupulous, cynical and even criminal elements.

The purpose of this testimony, I'll define diversion as the unauthorized transfer of prescription drugs from its intended recipient to other unauthorized destinations.

Getting back to my first point for a moment, permitting diverted drugs into the United States market will destroy the current regulatory system. The U.S. regulatory scheme is built upon almost a century of solid science and experience designed to protect Americans from unsafe and unproven drugs. But if anybody can buy anything from anyone without a prescription, the entire regulatory regime collapses. Congress may as well just abolish the FDA.

The second issue is linked to the first. Those who suggest that the FDA merely become advisory or gold standard agency in other words, just setting advice with regard to what the standard should be without any enforcement at all ignore the clear danger of counterfeits. Well, counterfeits continue to be a minor problem. They're fast growing in the United States and they will overwhelm legitimate markets if current regulations are abolished. There is simply no way for consumers to distinguish between legitimate and counterfeit goods unlike going down to K Street and buying a \$30 Rolex. There is no way a consumer can tell a legitimate pharmaceutical from a counterfeit.

In countries where diverted pharmaceuticals are available, counterfeits have soon followed, displacing the legitimate products. Diversion is merely a Trojan horse for counterfeits.

This is not a free trade issue and I really want to emphasize this. Any foreign manufacturer who meets U.S. standards can sell legitimate goods in the United States right now and I don't think anybody wants to change that. But without regulation counterfeits can wreck even the legitimate import market.

The third point is that cost of drugs will not significantly decline for consumers if diverted prescription drugs are permitted into the United States.

In other areas where diversion is permitted, for example, in over-the-counter pharmaceuticals and other consumer products, the prices to consumers are only slightly below normal retail. It's the middle men who pocket enormous profits. In South Africa, for example, half of all the pharmaceuticals dispensed by the South African government itself are stolen. These goods that are stolen never entered the bloodstreams of indigent Africans, but rather are sold for huge profits abroad and in South Africa. The stolen and diverted goods are replaced in South Africa with counterfeits.

There is no cheap or easy solution to these problems we've discussed today, but we cannot jeopardize the safety or health of U.S. consumers by artificial and dangerous gray market import schemes. We need to have prescription drug coverage for all those who really need it, rather than jeopardizing the safety and health of all of us.

We need more effective enforcement, not the abolition of enforcement. In short, any proposal to permit the unregulated imports to prescription drugs will destroy the U.S. regulatory scheme, jeopardize the safety and health of millions of Americans, and not result in significant cost savings to American consumers and I thank you and would look forward to your questions.

[The prepared statement of Donald DeKieffer follows:]

PREPARED STATEMENT OF DONALD DEKIEFFER, DEKIEFFER & HORGAN

INTRODUCTION

Mr. Chairman and members of the Subcommittee: I appreciate the opportunity to appear before you. I am Donald deKieffer, attorney at deKieffer & Horgan in Washington D.C. My firm specializes in the practice of international regulatory law. I have over thirty years of experience in trade law and policy development and have worked for more than a decade in tracking and investigating international diverters. Today I will testify regarding the diversion and global counterfeiting of pharmaceutical products. Although many of the clients I represent are pharmaceutical companies, I am neither speaking on their behalf nor on behalf of the pharmaceutical industry in general.

The objective of my testimony is to inform this committee of the existence of an active pharmaceutical diversion trade and to demonstrate how failure to control this practice opens the door for the entry of counterfeit drugs into the United States. I will first present a foundational background on the law regarding drug imports. Secondly, I will discuss the nature of the diversion problem and its influence on criminal activity, the pharmaceutical market, and governmental regulatory agencies, in particular the FDA. Thirdly, I will propose possible avenues to pursue in the development of solutions to these problems.

OVERVIEW

Drug Classifications

Controlled substances are classified into five different schedules. The schedules are distinguished from each other based on the potential for drug abuse. Schedule I identifies substances with a high potential for abuse that do not currently have an accepted medical treatment use in the United States, such as heroin and marijuana. Schedules II through V are controlled substances with legitimate medical purposes, such as Ritalin and Valium. Schedules II through V also include "lifestyle drugs." These substances, such as Viagra, target disorders affecting the quality of life rather than specific diseases. Lifestyle drugs are commonly abused prescription substances. Additional controlled substances, such as OxyContin, which are not lifestyle drugs, are also abused.

Diversion

International diversion is the importation of products originally intended for distribution in another country. Pharmaceutical diversion involves substances classified in schedules II through V. A classic diversion scheme begins when drugs that are produced in the United States are either sold at low prices or are given philanthropically to other countries. Corruption and fraud in the countries of destination permits third parties to obtain large quantities of U.S. produced drugs at low costs. These drugs then make their way back into the U.S. market for resale at going market rates, thus generating large profits for the diverters.

Closely related to diversion is the practice of parallel importing, which is the importation of patented drugs by third parties without the authorization of the patent owner. Drugs produced by U.S. pharmaceutical companies are available for a lower cost in other countries where the foreign governments fix pharmaceutical prices. Diverters purchase these drugs abroad and redistribute them in the U.S. market, thus undercutting the U.S. market price and making a tremendous profit.

Another subcategory of diversion is smuggling. While diverted products re-enter the country under the guise of legal imports, smuggled drugs are routed into the country through illegal means. Smuggling is the preferred means of re-importing diverted drugs. These pharmaceuticals mainly come across customs borders or through the mail system with fraudulent documentation. The sheer volume of diverted drugs entering the country prevents customs officials from detecting or seizing more than a mere fraction of them.

Counterfeiting

Many foreign countries permit the cross border exchange of imitation patented drugs manufactured in countries other than the United States. Counterfeit drugs are a tremendous problem in countries with lax import regulations. Counterfeit pharmaceuticals are often purchased to replenish the dwindling drug supplies that result from diversion. These counterfeits are not subject to any form of production regulation, and once they get mixed into the system they are essentially indistinguishable from the legitimate product. While counterfeit drugs are not yet rampant in the United States, the loosening of import regulations leads to a climate that increases the potential for counterfeit distribution.

Diversion is a Trojan Horse for counterfeits. Drugs are no longer part of a regulatory infrastructure once they leave the control of the originally intended recipient and enter the channels of diversion. Many of these drugs pass through countries where there is rampant corruption and fraud in the drug industry, and counterfeits are in abundance. Because there is no way to monitor where the diverted products have been or how they have been handled, it is highly likely that counterfeits will unknowingly be mixed with diverted drugs. Counterfeit products then enter the U.S. system mixed with legitimately produced U.S. drugs.

Counterfeiting in the U.S. is already existent to a certain extent. For example, between 1991 and 1995 the FDA and U.S. Customs officials seized enough evidence to incriminate Flavine International Inc., a New Jersey based company, in a counterfeit drug scandal. Flavine bought bulk amounts of veterinary antibiotic ingredient base and other human antibiotics from an unapproved source in China for considerably less than the price of the legitimate products. Flavine then resold the material to unsuspecting U.S. drug companies at an inflated rate. The scheme posed a risk to animals and humans because the counterfeit drugs were of unknown potency and quality. Six patients in Denver suffered toxic reactions.

More recently, the FDA has been investigating cases of counterfeit injectable drugs. Instances of counterfeit Serostim, a growth hormone used by AIDS patients, Nutropin, also a growth hormone, and Neupogen, a cancer drug, have been detected in the past month.¹ FDA investigations are ongoing and it is not yet clear whether the drugs were produced in the United States or overseas. At least some of these products ended up in U.S. pharmacies and were actually distributed to customers who experienced adverse reactions.²

CURRENT REGULATIONS AND LAWS REGARDING DRUG IMPORTATION

The federal government has jurisdiction to control pharmaceutical importation into the United States. The FDA, DEA and U.S. Customs are the federal agencies primarily responsible for overseeing drug import regulation.

The law effectively prohibits the importation of any drugs, including foreign made versions of U.S. approved drugs, that have not received FDA approval to demonstrate they meet the federal requirements for safety and effectiveness.³ FDA approved drugs can only re-enter the country if they are being shipped directly back to the manufacturer. When customs officials receive a shipment that contains non-approved pharmaceuticals intended for commercial distribution they notify the local FDA district, and the FDA assumes responsibility for deciding whether or not to seize the goods. FDA personnel are also responsible for monitoring mail importation. Customs officers from the customs mail division will examine a parcel and set it aside if it appears to contain a drug that the FDA has specifically requested be held or an FDA-regulated article that appears to represent a health fraud or an unknown risk to health.

The rules governing personal importation of approved drugs from foreign countries vary slightly. Congress recently stipulated that a United States resident may import up to fifty dosage units of a controlled medication without a valid prescription at an international land border.⁴ Medications must be declared on arrival, be for own personal use, and be in their original container. The FDA has the ability to exercise discretion in the enforcement of this law and may permit the entry of unapproved drugs under extenuating circumstances, such as the continued treatment by a foreign doctor. However, this policy does not apply to foreign-made chemical versions of drugs available in the U.S. The FDA cannot assure that such products have been properly manufactured and are effective. Their use would present an unreasonable risk. Additionally, the FDA reserves the right to refuse entry or seize any drug it considers unapproved and, therefore, illegal.⁵

The DEA has recently contributed additional regulations designed to help control pharmaceutical imports from foreign markets. According to the DEA, consumers must have valid prescriptions to legally obtain controlled substances. Consumers cannot legally purchase controlled substances from foreign Internet sites and have

¹ Melody Petersen, *3 Fake Drugs Are Found in Pharmacies*, N.Y. TIMES, June 5, 2001 at <http://nytimes.com/2001/06/05/business/05DRUG.html>.

² Douglas Pasternak, *Knockoffs on the Pharmacy Shelf: Counterfeit Drugs are Coming to America*, U.S. NEWS, June 6, 2001 at <http://www.usnews.com/usnews/issue/010611/usnews/couter.htm>.

³ 21 U.S.C. § 331(d) (2000).

⁴ 21 U.S.C. § 956 (a) (2000).

⁵ U.S. Customs, *Importation of Prescription Medication/Drugs Consumer Alert*, available at <http://www.customs.ustreas.gov/travel/med.htm>.

them shipped to the U.S. unless the consumer is registered with DEA as a controlled substance importer and acts in compliance with DEA requirements.⁶

NATURE AND CONSEQUENCES OF PHARMACEUTICAL DIVERSION

Promotion of Criminal Conduct

Failure on the part of the U.S. government to control pharmaceutical diversion encourages criminal behavior both domestically and internationally. The ease with which pharmaceutical drugs are smuggled across the border makes diversion enticing as a low-risk criminal activity with high economic returns. Diverters and counterfeiters are able to exploit the American public because of increasing frustration surrounding the high cost of medications and a market that has been traditionally free from unapproved or dangerous products. The proliferation of an American gray market, therefore, invites the theft of American drug products in foreign countries, thus completing the vicious circle of criminal conduct.

The diversion trade also facilitates the abuse of prescription drugs in the U.S. An estimated four million citizens in the United States are addicted to prescription drugs.⁷ Many of these products are lifestyle drugs, such as Viagra, weight control products, or tranquilizers. There is also a serious problem with the misuse of other legitimate medications. For example, the pharmacological effects of OxyContin, a central nervous system depressant designed principally as a pain medication for cancer victims, make it a substitute for heroin.⁸ OxyContin overdoses have been the cause of over forty deaths on the East Coast in the last year.⁹ Much of the illegal OxyContin supply comes from diverted sources. Diversion increases the ability of individuals to receive drugs through improper channels without a prescription, thus fostering the opportunity for misuse of these products.

Destruction of the Pharmaceutical Market

Diverters regularly import undetected pharmaceuticals into the United States. Since 1997, more than 4,600 foreign drug manufacturers have shipped to the United States without being inspected by the FDA.¹⁰ Additionally, Congress has relaxed the regulations on the importation of controlled substances by allowing U.S. citizens to legally import limited amounts of price-controlled drugs from Mexico and Canada for personal consumption.¹¹ Slackening of import standards increases the likelihood of diverted drugs devastating the U.S. pharmaceutical market.

Diversion, in the form of parallel importing, is a violation of intellectual property rights. Included in most patents is the exclusive right to the use, including importation and exportation, of the patented good. Intellectual property rights are the financial basis of the pharmaceutical industry. The more diverted and counterfeit drugs permitted to enter the country, the less control the patent holders maintain. Taking away the intellectual property rights of the pharmaceutical industry will render patents meaningless and will create major financial setbacks for the market. Pharmaceutical companies may have to freeze research and development and may not be able to financially justify pouring resources into the creation of new and improved medications.

Diverted drugs destroy the predictability of supply and demand in the pharmaceutical industry. The U.S. government does not artificially control drug prices. The U.S. pharmaceutical producers have not traditionally competed with international drug distributors, principally for regulatory reasons. The result has been that pharmaceutical companies have freedom to incidentally set prices for the products they develop. Consequently, as happens in many different markets, drug prices are disproportionate to actual production cost. However, inflated prices are necessary to offset the marketing cost of the specific product, to finance research and development of new products, and to subsidize medical assistance to struggling nations. In a regulated system such as this, the pharmaceutical industry bases production on predicted market needs. Diverters destroy the market balance when they enter unknown and unregulated surpluses of any product into the country through the chan-

⁶ Notice, Dispensing and Purchasing Controlled Substances over the Internet, 66 Fed. Reg. 21,181 (April 27, 2001) available at http://www.deadiversion.usdoj.gov/fed_regs/notices/2001/fr0427.htm.

⁷ John Smith, *A Prescription for Drug Abuse*, WASH. HERALD, May 20, 2001.

⁸ National Drug Intelligence Center, *OxyContin Diversion and Abuse*, (January, 2001), available at <http://usdoj.gov/ndic/pubs/651/overview.htm>.

⁹ *Id.*

¹⁰ FDA Admits to Lacking Control Over Counterfeit Drug Imports AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS available at <http://www.ashp.com/public/news/breaking/counterfeit.htm>.

¹¹ 21 U.S.C. § 956 (a) (2000).

nels of diversion. Companies are unable to maintain any sort of meaningful records regarding the distribution and consumption of drugs and cannot react proportionately to the market need.

Diverters exploit the price disparities between U.S. and foreign pharmaceutical prices. Pharmaceutical companies provide drugs to other countries either philanthropically or at much lower prices than they are sold domestically. Diverters capitalize on this price differential by obtaining low priced drugs in other countries. They are then able to undercut the market price when re-selling drugs back in the U.S. This practice generates a surplus in the American market and prevents pharmaceutical companies from meeting their projected sales quotas. Ironically, customers are not the ones financially benefiting from diverted drug sales. Diverted drug products often barely undercut the normal retail prices. However, because diverters obtain the drugs at a fraction of U.S. resale prices, the diverters assume a tremendous profit while the customers reap only a fractional benefit.

The entrance of diverted drugs and counterfeit products into the market creates a financial liability for the pharmaceutical industry. Prescription drugs carry a strict liability for the producers. Strict liability means that drug companies are completely accountable for their products and must bear the cost of lawsuits and fines, regardless of any question of negligence. Counterfeit drugs may easily be mixed with diverted products. Counterfeit drugs are dangerous because they are entirely foreign substances masquerading as the genuine product, and they may not even consist of the same ingredients that they profess to contain. There is a high likelihood that customers who unsuspectingly ingest these products may be adversely affected. It is difficult, even for a professional, to distinguish between counterfeited and legitimate drugs. Since these counterfeit products are difficult to distinguish, companies may find themselves liable for situations that were not of their own causing. The potential financial hit that the pharmaceutical industry will bear, as a result of liability, will adversely affect the financial stability of U.S. drug companies.

Diversion also affects world pharmaceutical markets and finances criminal conspiracies. Many countries, such as South Africa, Israel, Russia and the Philippines have open borders with respect to the importation and exportation of pharmaceutical products. Open border countries have lost strict regulatory control of their drug markets. For example, in South Africa over fifty percent of the medication supplied to the government ends up stolen. Open border countries have also experienced a corresponding surge in counterfeit medicine entering under the guise of parallel imports. Frequently, the counterfeits enter the country as a means of replenishing the drug supply depleted due to the diversion of the legitimate drugs to more lucrative markets in Europe and America. Consequently, the medicines intended for a particular population are not getting to the people that need them; in their place, false and dangerous counterfeits are being provided, and criminals reap the financial benefit.

Undermining the FDA

The American public is currently frustrated with high priced pharmaceuticals. There is an outcry for access to pharmaceutical products that are cheap, readily available, efficacious, and safe. However, permitting diversion and parallel imports is not a viable solution. Safe and efficacious products come at a cost. The entrance of diverted and counterfeit drugs into the U.S. will destroy drug control regimes currently in place and the FDA will lose its ability to monitor and control drug production and distribution in this country.

Increased diversion traffic through inefficient monitoring at the border will prevent the FDA from controlling drug entry and distribution. Unchecked pharmaceuticals currently enter the country through the mail system and across the Mexican border. Due to the sheer volume, this influx of drugs basically goes unmonitored by federal regulatory groups such as the FDA. As a result, drugs in this country are being distributed and sold without proper authorization. This diminishes the ability of the FDA to control the distribution of drugs. Citizens are able to access "lifestyle" drugs and potentially addictive substances without prescriptions or the direction of a physician. Consequently, the FDA is losing its ability to manage prescription drug use.

Counterfeit drugs present a danger to citizens because the FDA is unable to monitor the products for quality and safety. Counterfeit drugs, principally produced in countries such as India, are imitations of U.S. made products. However, it is impossible to know for certain what these medications contain, how they were produced, where they were stored, or the potential side effects of ingestion. By allowing the diversion trade to persist, the likelihood of distribution of these potentially lethal medications increases, and the FDA loses the ability to regulate the quality and safety of products being distributed to the unsuspecting U.S. public.

Diverted drugs that leave the control of the original distributor place consumers in jeopardy because the means of shipment and storage are unregulated. Diverted drugs enter and exit the hands of multiple unknown parties before they eventually reach a consumer. These drugs are commonly stolen in bulk from government agencies in foreign countries and are routed through countries such as Mexico before they reach consumers in the United States. Most drug products have specific instructions regarding storage temperature and expiration date. With diverted drugs, there is no guarantee that the products were properly handled during shipping and storage. The FDA has always exerted strict controls on the production and distribution of drugs in the United States. Consumers have learned to expect pharmacies and drug distributors to provide safe medications. Allowing diverted drugs into the country will destroy the FDA's ability to guarantee safety and will increase the danger to consumers who may unknowingly purchase and ingest these products.

Counterfeit drugs that enter under the guise of parallel imports likely come from unapproved locations. Both counterfeit drugs and diverted drugs are huge risks to the citizens of this country. The FDA has traditionally been able to approve the production location of drugs and foreign products. When drugs are smuggled into the country, there is no way of knowing where they have traveled. Additionally, counterfeit drugs entering the country through diversion may have been produced anywhere. The FDA is, therefore, losing its ability to control and monitor the production sites for pharmaceuticals being imported into this country.

Diverted drugs may contain incorrect informational material and directions or may be mislabeled entirely. Medications are, of course, dangerous when misused and require specific instructions as per their usage. Divergence from these requirements may prove extremely harmful and potentially lethal. Diverted goods are often taken from their original packaging and distributed to many different importers. The potential is high that drugs may be mislabeled or put into packages that lack the appropriate informational material. As the diversion trade increases, the FDA will in turn lose control over the packaging and instructions accompanying large quantities of drugs in this country.

Additionally, the diversion trade destroys systems of record keeping for the U.S. drug industry. With products being illegally mailed into the country and smuggled across the borders, it is impossible for the FDA or the drug industry to keep track of what is currently on the market. This makes it easier for people to obtain drugs illegally and promotes the abuse of prescription products.

POTENTIAL SOLUTIONS

There needs to be better cooperation between the government agencies in charge of enforcing laws relating to diversion and counterfeit trade. According to a report issued by the U.S. General Accounting Office, the efforts of the FDA, DOJ, DEA and Customs do not always support each other.¹² For example, sometimes the FDA releases packages of drugs detained by Customs in an effort to conserve resources. These kinds of actions are counterproductive, undermine the law, and send mixed signals to the individuals involved.¹³ Laws have been put in place to control diversion; however, it needs to be clear who is in charge of enforcement. Efficacious systems of detection and seizure as well as substantial penalties for abusers must be implemented and enforced.

Foreign Internet pharmacies dealing in illegal imports need to be eliminated. An abundance of Internet pharmacies situated in foreign countries advertise prescription drugs. These sites do not require individuals to have a prescription from their doctor in order to obtain drugs. Although DEA regulations and the Controlled Substances Act allow individuals to bring limited quantities of controlled substances into the U.S. for personal use, these regulations do not apply to shipments into the U.S. from foreign Internet pharmacies. It is illegal to purchase drugs from such sites. These pharmacies are aware that they are engaging in illegal activity. Many sites explicitly justify their practice and include instructions on how to avoid having the packages seized by U.S. Customs. This problem needs to be attacked at the source. There must be a crack down on foreign Internet pharmacies dealing in illegal importation.

The government should look for solutions to help support/subsidize providing affordable prescription drugs for the elderly and others who are unable to afford necessary medications. The diversion trade seems to be supported in part by frustrated Americans seeking cheaper drugs. It is contended that many of these individuals are

¹²U.S. GEN. ACCOUNTING OFFICE, REP. TO CONG. REQUESTERS GAO-01-69, INTERNET PHARMACIES 17 (2000).

¹³*Id.*

seniors who are on tight budgets and cannot afford the medications they require. The government should consider providing a means-tested subsidization for U.S. citizens unable to afford the medications they require. Providing medication to those who are feeding the diversion market will reduce the demand for smuggled drugs.

Penalties for prescription drug abuse must be increased. It is currently very difficult to detect prescription drug abuse, and many people fail to even recognize it as a crime. Harsher penalties may decrease the demand for diverted pharmaceuticals and naturally cause that market need to decrease.

Finally, there needs to be cooperation between government agencies and the pharmaceutical industry in creating better systems for overseeing philanthropic drug distribution in other countries. Much of the aid that is sent to struggling countries is well intended. However, it has been proven time and time again that these countries lack the infrastructure and integrity to properly distribute the products to the intended recipients. It is counterproductive to provide mass quantities of free or low-priced medication to countries that cannot properly handle or distribute it. Until a more reasonable infrastructure can be put in place, bulk deliveries of U.S. pharmaceuticals to underprivileged countries should be severely restricted.

There likewise needs to be a better system of tracking drugs destined for distressed markets where there is a possibility of corruption or diversion. There are FDA approved means of marking both drugs and packaging that would allow customs officials to quickly and efficiently monitor what crosses the border. Such a system would help catch diverted products before they entered the market.

CONCLUSION

In summary, drug diversion is a crime. Its occurrence is increasing. By permitting this practice to continue, the government will open the way for counterfeit drugs to enter the U.S., foster criminal conduct both internationally and domestically, harm the pharmaceutical market, and undermine the regulatory structure of the FDA. Measures should be taken to recognize and address these issues.

Mr. GREENWOOD. We thank you. All of you gave excellent testimony.

The Chair recognizes himself for 5 minutes for questioning. Let me address a question to Dr. Shepherd. The law of unintended consequences tells us that when we try to fix something we usually cause another set of problems. Even though we will try to minimize that as much as we can, one of the concerns that will undoubtedly be raised as we try to tighten the Mexican-U.S. border will be—what about the poor senior citizen who doesn't have access to prescription drugs in the United States and goes over to get the legitimate drug for legitimate purpose and are we going to foreclose that opportunity?

Can you give a little information on to what extent you know, obviously, you know a lot about it, who it is that's going back and forth. Is there, in fact, (a) much in the way of legitimate seniors going over for legitimate drugs and acquiring safe products as a result of that, and is there actually much of a savings when they do that?

Mr. SHEPHERD. There is a legitimate market for seniors especially in the Presidio or McCallum, Texas area where they go across over to Presidio and get it because there's a lot of snowbirds that come down from the Midwest and New England, spend their winters down there and they purchase a year's supply of Mexican drugs and take them back with them, where they're going. Laredo, we didn't see a lot of seniors in that market area and Juarez, I'm not quite sure. El Paso area. But you're right, there is a legitimate market where a lot of seniors do take advantage of it and do get them.

The question about whether the drugs they buy over there is safe, I don't know. I don't know if they're buying—

Mr. GREENWOOD. How about the cost? Is the savings as significant as we've heard?

Mr. SHEPHERD. The savings are significant, but it's product-dependent. It very much varies by each individual product. Some products in Mexico are more expensive than here. Some products may be a dime or more or \$2 less in Mexico. But there are some products where it could be 4 or 5 fold difference in price.

Mr. GREENWOOD. How do you recommend then that we deal with that issue, because it's a legitimate one and I am hopeful that we will be able to provide a prescription drug benefit under Medicare, but even that won't necessarily solve the problem because there will still be some——

Mr. SHEPHERD. That would be my recommendation, if we had a prescription drug benefit I think that would dry up a lot of the market. There's another market over there that presents a bigger issue and that is families who reside on this side of the border who visit physicians on the other side of the border where the family is split between both countries. That's a huge problem. And I was at a conference not too long ago where the Mexican Blue Cross and Blue Shield was lobbying Texas to establish health care system that U.S. residents could sign up for their health care insurance in Mexico and therefore use Mexican providers and Mexican pharmaceutical products. That just opens up all kinds of other problems when you think about it. Obviously, the best way to go would be some kind of prescription drug benefit for the elderly or the poor or indigent poor so that you could bring them back and forth, but it is a problem. Both those populations.

Mr. GREENWOOD. Let me just question Mr. Trundley if I may on the counterfeit problem which is a rather different, but important aspect of this hearing as well. I'm not sure I heard a lot in the way of recommendations from you. I saw a lot of parade of horrors that is very worrisome, but what are your thoughts about how we get a handle on this. How do we prevent the flooding of the U.S. market with these counterfeit products?

Mr. TRUNDLEY. Well, first of all, Mr. Chairman, you need strong legislation in place. Robust legislation to deter and help prevent the incident.

Second point I'd like to make is——

Mr. GREENWOOD. By that do you mean tough criminal penalties?

Mr. TRUNDLEY. Tough criminal penalties which prevents and also legislation to prevent the reimportation of goods as well into the United States. Tough criminal penalties and also to support the law enforcement effort.

I would like to echo the point made by Jim Christian, my colleague, it is becoming now more and more essential to have field operatives in the countries where the problem lies. For instance, the British government doesn't employ the FDA equivalent agents abroad. That means, Mr. Chairman and members, that the only people who are combatting this counterfeit crime at the point of manufacture are the pharmaceutical companies' security representatives. That means that we are conducting inquiries by remote control 12,000 miles away and the sheer volume and scale of it means that it's becoming more and more difficult and we're acting on our

own with little or no support from the British or the U.S. governments.

Mr. GREENWOOD. Mr. deKieffer, the thought that occurred to me as you were testifying about this situation in Africa, as the pharmaceutical companies in this country who have I think rather generously and compassionately decided to provide very low cost AIDS drugs to the African continent where they're gravely needed, what's going to happen in terms of diversion? Are there procedures in place to prevent bad guys from getting their hands on these drugs, sending them back, reimporting them to the U.S. at a tremendous profit and then providing bogus drugs to AIDS people that AIDS patients who will then obviously get no benefit at best?

Mr. DEKIEFFER. That's a significant danger. In fact, the security measures that have been taken to date have to be taken by the companies themselves because of the demonstrated ineffectiveness of the security measures that have failed already all over Africa. Some of the philanthropies that have distributed goods there have also been able to document the fact that massive amounts of goods that were intended for good and philanthropic purposes have not wound up where they're supposed to be, so yes, there's a very great danger that a lot of the products that are being distributed in Africa will not remain in Africa and where they will all end up is anybody's guess, but we do know that substantial amounts of goods that are currently being distributed in Africa, including probably the most advanced country in sub-Saharan Africa, South Africa, never wind up or don't stay there. They wind up in third markets. And because South Africa is awash in counterfeit drugs as well, there's a significant chance that some of those products could wind up in this country as well, perhaps via Mexico.

Mr. GREENWOOD. Thank you. The Chair recognizes the gentleman from Florida for 5 minute.

Mr. DEUTSCH. Thank you, Mr. Chairman. I think most of you sat through the testimony prior to this, the other panels. And I guess one of the questions I have in terms of the issue of the counterfeit prescription drugs, I don't know the exact number, no one knows the exact number, but just from our oversight visit, a large percentage, maybe even up to 90 percent of the literally millions of products being sent by mail into the United States are prescription drugs, very well might be from your companies. Now or at least labeled as if they were from your companies. I guess my question is we're talking about literally tens of thousands of drugs and we've seen the labels and again from our perspective, from a naked eye perspective, we can't tell the difference. Obviously, the labeling is very effective. Where are those drugs coming from? The tens of thousands of ones on a daily basis or the thousands on a daily basis that are coming into the United States via the mails, who's producing them? Are a majority of them counterfeit? Are they being produced overseas in facilities of your companies? Are they gray market overseas? I mean anyone want to attempt to answer?

Mr. GLOVER. I'll try to answer that. It's difficult to answer that question directly. What we have seen is what we do know is that in March of 2000 and January of about 2000, just recently as well, there have been substantial actions in Taiwan of these kinds of factories that we have seen so we know that that is a location there,

so we know that there's a problem there based on the actions that we've seen so far. The problem that we have is that it is an international problem and it takes many forms. It starts out perhaps even as legitimate product. It's just bulk active. It then maybe moves as was said to a free trade zone. It's maybe tabletized. It's not really counterfeit maybe until somebody slaps a label on it that says it's from Company X when it indeed is not Company X. And then, of course, there's an enforcement problem for the same reason. We have the same enforcement problem here that you have say in the narcotics traffic.

Mr. DEUTSCH. Let me just interject, we're going to try to get through 5 minutes of questions, and the Chairman has been very liberal and I appreciate that on this issue, but what I'm trying to really get a sense of is that there's no question and you've shown it by your testimony that there's absolutely, there are people who are counterfeiting your products. And illegal enterprises that are doing it. Obviously, they're making money from it and we're not getting all the enforcement. But I guess what I'm saying at least this is a component of this hearing, but the issue what this subcommittee is really looking at is literally this phenomenon of millions of product coming into the United States via the mail and some of that product is at least labeled as your product and I find it not easy to believe that all of that's counterfeit because if it was I think you folks would a lot more concerned about it, that it really is a product of your companies and whether it's produced overseas, I mean a lot of the product that Novartis sells in Hong Kong or in Taiwan or in South Africa is legitimate Novartis product. I would assume the vast majority of it is Novartis product. I mean Mr. Christian, do you want to respond to that?

Mr. CHRISTIAN. Yes, I'd like to make a quick comment. This is a counterfeit Voltaran ampoule. Last year in Colombia working with the authorities we seized 6 million of these. That is 7 or 8 times what is sold in Colombia in a year. We see 6 million. That's not what was made in Colombia. This is what we caught, 6 million. To answer another part of your question because we're concerned about counterfeit product. We're concerned about expired product. I have here a genuine antibiotic with an expired label. We seized millions of these. I have here what they did with them. They put them in hot soapy water and they took the labels off and I have here the labels that we seized with the product and these go right around, look just like genuine and they have a new expiration date. So when those products come in, you have to be concerned yes, about counterfeit products, but you also have to be concerned about expired products, adulterated products. We don't have time, but I have overheads that show pieces of glass and other foreign material in vials and ampoules.

Mr. DEUTSCH. Let me try to follow up specifically on that though, so again, we're really talking about millions of product coming to the United States and your assessment is that most of that is effectively fake or inappropriate?

Mr. CHRISTIAN. No, our assessment is that the potential is there for in that grouping that you call those millions of packages coming in at Dulles and JFK and Oakland, that they will contain a rep-

representative sample that is growing of counterfeit, of expired, of mislabeled, of adulterated product. There is no doubt.

Now what you're probably looking for is it 5 percent, is it 50 percent? We don't have that number, but we are very, very confident that the percentage is growing.

Mr. DEUTSCH. Let me, go ahead, I'm sorry.

Mr. TRUNDLEY. I would just like to add to what Mr. Christian has said that even though the product might be genuine, even though it might not have met its expire date, we cannot be certain that it's been stored in the appropriate conditions. If a particular life saving drug has to be stored at 5 degrees Centigrade, how do we know unless it's gone through the legitimate distribution and supply chain that it's been stored in those conditions and hasn't been left on the dockside somewhere in Central and South America in baking hot conditions? And it's then shipped into the United States. It might be perfectly legitimate and bonafide a product.

Mr. DEUTSCH. I guess just one final question about this. It's probably the most visible website sale is for Viagra and we don't have a representative from Pfizer here today, but is—what would your assessment be that most of the stuff that is being sold on the Internet today for Viagra, is that Viagra or is that something beyond Viagra.

Mr. CHRISTIAN. I can comment on that. I think that there are more than 20 pharmaceutical companies making Viagra in India. Now one of them and because they honor the process patent, they are allowed to ship to other countries that honor the process patent which takes in some Middle East, African, Argentina, Brazil, Uruguay, limited number of countries that honor the process patent. One of the 20 plus companies that manufacture Viagra shipped 40 tons in the year 2000 of Viagra, 40 tons bulk material. Now I can tell you that the Middle East and sections of Africa and Argentina, Brazil and Uruguay are not using 40 tons of Viagra and that's only one of more than 20 companies that shipped in 2000.

Mr. DEUTSCH. Thank you. Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes the gentleman from Michigan, Mr. Stupak for 5 minutes.

Mr. STUPAK. Thank you, Mr. Chairman. What happens to your expired products, Mr. Christian or anyone on the panel? If a product expires, how are they falling in the hands of these counterfeiters then who are soaking off the label and putting a new label on there?

Mr. TRUNDLEY. Most companies, in fact, I'm sure that all companies have a policy of returning the expired product to the companies by the distributors and the companies then destroy them. The problem lies when the distributors sell them on the more unscrupulous wholesalers and dealers who may be just using it as a front to copy the product, to copy the packaging and design and putting in the counterfeit rubbish inside the blisters.

Mr. GLOVER. I'd like to comment on that for a minute.

Mr. STUPAK. Sure.

Mr. GLOVER. A lot of the times you have a situation internationally. We've had one particular experience internationally where a company was to destroy product when it expired. We found out that the product—we ultimately found the product on the market.

We conducted an investigation, surveillance and what we found was that in this particular instance, there were two trucks. The truck would take the product to the dump to be destroyed and it would instead of going into the dump would be passed on to another company that brought it out, so there are unscrupulous people out there. We have processes in place, but sometimes they're avoided.

Mr. STUPAK. Dr. Shepherd, could you go back to the Oxycontin issue we were talking about earlier.

Mr. SHEPHERD. Right.

Mr. STUPAK. Customs seems to know that these vials are coming in or packages of 50, they're packaged in Mexico and they're coming across, but DEA did not seem to understand that today.

Can you elaborate a little bit more on that whole issue there?

Mr. SHEPHERD. I really can't talk for why DEA wouldn't know because I don't work for DEA—

Mr. STUPAK. Right.

Mr. SHEPHERD. But as a researcher in Laredo, I spent 3 months down there collecting data, the only agents I saw down there were U.S. Customs Agents. I don't know, ever recall seeing DEA Agents present, but they may have been present.

Mr. STUPAK. But it's your testimony is that it really comes across already packaged in these 50 or less or packages of 50?

Mr. SHEPHERD. Oxycontin was coming across in a vial of 50. We saw it.

Mr. STUPAK. Were they stopped at the border by Customs Agents or anything like that?

Mr. SHEPHERD. When we were collecting the data last month, they went to the Customs Agent up front who screened the amount of drugs coming across. Basically, he just asked the person did you buy any prescription drugs. If the person said no, and this was the extent of it, the person said no, they were passed on through. If the person was honest and said yes, they were referred back over to us where we asked them to fill out a little questionnaire of the types of drugs and what you purchased. If the person said yes and the participant, the Agent indicated they had purchased more than the 50, then we never saw them. They went back to another room with a Customs Agent. And at that time the drug was either confiscated by the Customs or the person was asked to go back across the border and sell the drug back to the pharmacy which was—it's been a common practice.

Mr. STUPAK. But if I come up to the border I can have 50 pills of just about anything I want, right, as long as I don't go over that magic number of 50?

Mr. SHEPHERD. That's right.

Mr. STUPAK. Without a prescription? And I can just pass through.

Mr. SHEPHERD. Right, but I warn you, you better have a prescription from a Mexican doc why you're over there because you'll end up—

Mr. STUPAK. But that's not hard to obtain at all, is it?

Mr. SHEPHERD. No, that's not hard to obtain at all.

Mr. STUPAK. Part of the process.

Mr. SHEPHERD. That's very easy to obtain.

Mr. STUPAK. Okay.

Mr. SHEPHERD. We saw many people bring Valium and Oxycontin in 50 units at one time.

Mr. STUPAK. You indicated earlier that when you did your research in 1996 most of the things that came across the border were controlled substances and that the population buying it were not the senior citizens that we all hear about and we all want to help out. So what are the implications of these two findings? Do you have any reason to believe that the situation has significantly changed from what you found 5 years ago?

Mr. SHEPHERD. No.

Mr. STUPAK. Well, what are you seeing today, same type situation?

Mr. SHEPHERD. No. I have no reason to believe the situation has changed at all. I do—it's because it's so difficult to check when they come back into the border. The best way to check it is to stand in a pharmacy in Nuevo Laredo and watch the people enter and what they're buying. Stand next to a shopper and you can see the drugs being purchased, but when they come across, it's so easy to put them in your purse, put them in your back pocket and say I didn't buy anything and U.S. Customs will just let you walk on through.

Mr. STUPAK. If I may, Mr. Chairman, a couple more questions here.

To representatives of the drug companies, Ms. Durant of Customs, I think she was Customs, right, Customs, testified that Customs' Cyber Smuggler Center is playing a leading role in trying to crack down on these websites and they talked about the successful investigation in Thailand and how they closed down seven on-line pharmacy sites. I really wanted to ask her seven of how many of the hundreds that are out there from Thailand.

My question is with all the expertise we have on this Panel, has the FDA or the DEA ever contacted any of your companies in saying man, we've got a problem here with drugs coming through the Internet, mail orders, how would you approach it, do you have any—have they ever asked for any assistance or help or requested your input into this issue? Someone has been banging on them for 2 years to do something.

Mr. CHRISTIAN. We sometimes work with the Criminal Investigative Unit of the FDA, but it's a small unit. It was only founded 8 years ago approximately. To my knowledge, it has about 125 agents and they're domestically focused. I'm sure all over the issue that was in the New York Times on Tuesday. It's a domestic issue. It's internally. However, the threat to the United States lies internationally and that's why I mentioned that we need an international focus on this. It's a little late to throw investigative resources into the issue once the products are through Customs and within country. We need to be out there the way DEA is and the other agencies. Fighting to keep it up, not investigating it after it came in. But of course, we're talking limited resources, very limited resources when it comes to and that's one of the agencies that's divided between regulatory and law enforcement and in that particular case the regulatory people are the dominant part of that agency.

Mr. STUPAK. But I take it from your answer they never contacted you and said look, we're having problems with mail orders through the Internet and we have to do some work here. Do you have any suggestions, ideas on how we can best combat this?

I take it the answer is no.

Mr. CHRISTIAN. In fairness to them they have appeared at what John Glover referred to the prescription Pharmaceutical Security Institute, PSI. They have appeared at our meetings. They have given presentations. We have discussed issues. There is not daily, weekly or even monthly contact, but that's because we're concentrating our efforts in Latin America, in Asia, Eastern Europe, India. They're concentrating their efforts internally in the United States as far as I can tell.

Mr. STUPAK. Right, I agree, but all these websites, if you look at them, they're not U.S. websites. They may have a Post Office Box in some city, but when you really look it through, they're Thailand, Asia, Latin America.

Mr. CHRISTIAN. Exactly. We're missing that international focus on this particular criminal problem.

Mr. STUPAK. Good. Thank you.

Mr. GREENWOOD. The Chair recognizes the gentlelady from Colorado for 5 minutes for questioning.

Ms. DEGETTE. Thank you, Mr. Chairman. Following up, Dr. Shepherd, on Congressman Stupak's question, I'm sure you heard Ms. Nagel's testimony that she was aware of one instance of this—of the importation of less than 50 units of the Oxycontin and she knew about, she had heard about three instances that you talked about in your study. Now you just said here your researchers found numerous examples. I'm wondering if you can give me some sense of how much of the Oxycontin you saw being brought across the border?

Mr. SHEPHERD. No, I can't give you a sense of it. All I'm saying is that the way the study was done, the FDA study, when you ask the person if they purchased a prescription drug, they say yes or no. If they said no—

Ms. DEGETTE. They just went across.

Mr. SHEPHERD. They just went across. I mean if they had lied and said—

Ms. DEGETTE. I understand that. But—

Mr. SHEPHERD. If you go to the stores, you go to the farmacias and as a consumer over there and you watch the business, you know darn well and sure that there's more than that one person buying Oxycontin because you can see it coming across the counter.

Ms. DEGETTE. You can see based on what you're seeing sold in the farmacias on the Mexican side of the border.

Mr. SHEPHERD. Correct.

Ms. DEGETTE. Thank you. Let me talk about for a minute about a drug we talked about quite a bit in this committee last year and haven't so much lately and that's Rohypnol which, of course, is the date rape drug. It's my understanding that this drug is still made in Mexico by Roche. Do you know, is this drug still available in Mexico?

Mr. SHEPHERD. It's still available in Mexico by Roche.

Ms. DEGETTE. Do you have any sense as a researcher how much of the drug is consumed in Mexico?

Mr. SHEPHERD. No, I have no idea.

Ms. DEGETTE. Do you know if it's still coming across the U.S. border?

Mr. SHEPHERD. I have no evidence it's coming across the border.

Ms. DEGETTE. Have you talked to any of the farmacias down in Mexico about how much Rohypnol they're selling?

Mr. SHEPHERD. No, I've never asked.

Ms. DEGETTE. It might be a good question to ask next time you go down.

Last question for you, and that is the Texas Commission on Alcohol and Drug Abuse has found that the practice of allowing persons to buy controlled substances in Mexico and bring them back to the U.S. has contributed to Texas' drug abuse problem. Have you researched that and do you support the Agency's finding?

Mr. SHEPHERD. I've never researched that, but I really support the Agency's finding. Just from following the zip codes of people declaring the drugs and find out where they're going, we see, on our campus, we see a resurgence of Ritalin, especially during exam time when the youngsters want a stimulant. That's a common source.

Ms. DEGETTE. Do you know what the implications are of the Commission's findings?

Mr. SHEPHERD. No, I do not.

Ms. DEGETTE. Mr. Chairman, I'd ask unanimous consent to put the Texas Commission on Alcohol and Drug Abuse Report into the record.

Mr. GREENWOOD. Without objection.

Ms. DEGETTE. Thank you. I'd like to ask a question of our three pharmacy representatives here, that is, I'm sure, I think you were all in the audience when Mr. Hubbard of the FDA testified that they had made a recommendation to Secretary Thompson that the importation of all drugs should simply be halted with a very small exception for severe illnesses like cancer with very, very narrow guidelines. I'm wondering if you could each tell me whether you support that recommendation.

Dr. Glover?

Mr. GLOVER. Speaking from a health and safety perspective only, yes, I support it.

Ms. DEGETTE. Mr. Christian?

Mr. CHRISTIAN. Yes. I support it as well. I see the dangerous that are out there. It's a public health issue.

Ms. DEGETTE. Mr. Trundley?

Mr. TRUNDLEY. I concur. I also support it, but I would like to go one stage further and say that if you're going to go and introduce, if you're going to allow companies to import their products into the United States technology these days does provide for more advanced counter measures to protect the product in transit to make sure that it hasn't been tampered with, the computer chips, satellite tracking, radio frequency, identification tags affixed to the packaging in the cartons. These can be put on at the source of manufacture and tracked throughout their journey into the United States.

Ms. DEGETTE. Well, I think that that's an interesting point and would be an important precaution, for example, for the many legitimate pharmaceuticals that are imported company to company, but looking at the videotape of the Dulles facility, I think that it's going to be quite some long time before we can have safeguards like that for small amounts that are imported from individuals to individuals and I'm sure you would agree with me that the public safety would really say we just need to stop that right now.

Mr. TRUNDLEY. I do agree with you, yes. For the humanitarian cases, then we have to have something, a process in place.

Ms. DEGETTE. But it can be very narrowly drawn.

Mr. TRUNDLEY. Yes.

Ms. DEGETTE. Thank you very much, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentlelady. One final question from myself that I would address to Mr. deKieffer, Mr. Haislip and Dr. Glover, anyone else who wants to comment, specifically on the counterfeit problem.

I think it's clear that we have a sense of what we need to do about the question of drugs being, coming into this country by the mail. I think we have a notion of what we need to do on the Mexican border, but the counterfeit drug problem which is perhaps the most insidious of all is probably the most difficult to solve and looking for specific recommendations, Mr. Trundley has said what we need to do is pass robust legislation that makes for very severe criminal penalties for those who are caught and I don't know how often they're caught and I don't know whether—maybe you could shed some light on whether these counterfeiters in other countries that are found as a result of these investigations ever go to jail, but I'd like to know about that and I'd also like to know about specific recommendations for legislation.

Mr. DEKIEFFER. I believe as far as legislation or regulation, as was mentioned just a moment ago there is certainly now available to the pharmaceutical companies some rather high tech technology for at least being able to identify what are legitimate and not legitimate goods. These include all the way from the microchips that were mentioned a moment ago to even DNA markers inside actual pills so you can at least authenticate or track goods. This is a very practical thing that can be done and it could be done, I think, without legislation. It could be done by legislation. There are certain things that all of these companies do right now covertly, in other words, covert labeling, covert markings and things like that, but very often those get replicated very quickly, particular things like holograms. It takes 6 weeks now to have a hologram counterfeited or less. So as fast as they're able to put on new security measures, the bad guys figure out how to replicate them. But that's one of the answers to the counterfeiting issue. As has been mentioned today, since a lot of the counterfeiting goes on outside our borders, the thing that we need to do is be able to identify the counterfeit goods as they're coming into the country and whether that takes place offshore or at the border, by the time it gets into the country and whether that takes place offshore or at the border, by the time it gets into the country and gets into the distribution system, it is very, very difficult to do anything about it because it's going to go through six or seven hands. We saw this week one company that

was mentioned, it's Quality King, was mentioned in the New York Times article. Quality King was identified by this very committee in 1978 as one of the largest drug diverters in the country and now they're handling counterfeit products.

Here we have a company that's been in business for 25 years and identified repeatedly by this committee as still doing it and basically denying that they ever knew that they were dealing in counterfeit products. It's surprising.

Mr. HAISLIP. Well, Mr. Chairman, I think we have several problems and I'll try to be very quick with them. First of all, generally speaking, there aren't any—there is not any criminal law enforcement agency in most countries that's targeting that issue specifically. Therefore, there is not an international cooperating group that's targeting that activity specifically. I mean there may be exceptions to that now and then, but by and large that's the case. The third thing is that we do lack the international instruments and agreements to attack an international problem and the last thing I'd mention is that there's a danger of looking at this recent legislation on allowing reimportation that we really don't have the apparatus to detect this kind of counterfeit problem when it's going to be presented to our front door. I think there's a serious question there. So those are quick, very quickly some points that I would make.

Mr. GLOVER. Yes, I heard a word today a little earlier I think in the previous panel that I think kind of explains it. The word holistic. And that pretty much, this is an insidious international problem and I think from looking at the legislature, harmonizing, maybe agreements, conventions, those kinds of things, because again, if you look at what happens, we said the bulk starts say in China and India and when the bulk starts there, there's no problem with it. When it moves to other places, then it's not a violation. It only gets to be a violation as it starts to move in the stream and I say it goes from legal to civil violations to criminal violations once you slap a label on it. So that's—this thing is being constantly transforming, but I say enforcement, strong enforcement. I also say I think the political will, I talk about that. It's not this activity is generally not high on everybody's radar screen, it's not murder, it's not mayhem, it's usually a resource issue. They just don't have the issues because they're dealing with more serious problems so I think that's important. I think also awareness is a part of the problem. Some of the stuff that I see, I realize it won't deter everybody, but I think if somebody sees the stuff that we see and some of these labs that we see and they realize that that's actually the kind of stuff they're ingesting, I think it may have an impact on a few people so I just think a broad approach.

Mr. GREENWOOD. Thank you. Does the gentleman from Florida wish to—

Mr. DEUTSCH. Actually, just a housekeeping thing that if we can leave the record open just to submit some additional material.

Mr. GREENWOOD. The record will be kept open. We are blessed in this country by pharmaceutical products and medicine that save lives, extend lives, reduce pain and we're very fortunate indeed. But it's clear from this hearing that the United States is also awash in drugs that are misused and mislabeled and adulterated

and counterfeited and unprescribed and people are dying. People are dying in every State of this country as a result. This committee is going to act. We're going to act decisively and swiftly with legislation. We're going to expect a response from the Secretary of Health and Human Services. I will publicly ask for his responses in the next 60 days on this matter and you can be sure that the time that you have spent here with us today will not be wasted. We will not allow the time that has expired between 1978 to continue. We will act and we will act decisively. So thank you very much for your testimony. The hearing is adjourned.

[Whereupon, at 3:23 p.m., the hearing was adjourned.]

